Food·Drug·Cosmetic Law

Papers Presented
at Historic Meeting to Commemorate
THE FORTIETH ANNIVERSARY
of the Original Federal Food
and Drugs Act of 1906

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The FOOD DRUG COSMETIC LAW QUARTERLY is an original publication in the field of this law, which has a great and lasting value to all interested in its subject. For the QUARTERLY is designed to provide a constructive discussion of this law, through authoritative papers on it, in order to accomplish significant objectives. They are: (1) to create a better understanding of the law; (2) to further a due solution of its problems; (3) to achieve a high state of its operation, application and development; and (4) thus to secure a maximum attainment of its great remedial purposes, which are to safeguard the health of our people and to protect them from injurious trade deceit. In short, while this law receives appropriate consideration by the officers who administer it and the courts which enforce it, there remains the need for its basic study as a fundamental law of the land and for the objectives stated. And the QUARTERLY is intended to satisfy that need.

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FOOD DRUG COSMETIC LAW QUARTERLY

SEPTEMBER 1946

Preface...

THIS ISSUE of the *Quarterly* contains the proceedings of the important meeting on June 25, 1946, to commemorate the fortieth anniversary of the original Federal Food and Drugs Act of 1906, for a permanent record of it. This meeting was held in the Meeting Hall of the Association of the Bar of the City of New York, under the auspices of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association. It included three sessions. The morning session was devoted to a broad historical discussion of this act, and due tribute was then paid to its great founder, Dr. Harvey W. Wiley. The afternoon session considered the basic legal, health and industrial significance of the national food, drug and cosmetic law, instituted by this act. The climactic evening session consisted of tributes to the national food, drug and cosmetic law, by public leaders. The Surgeon General of the United States Public Health Service presided over it, and it was also sponsored by leading public organizations, including the General Federation of Women's Clubs and the National League of Women Voters. Illness prevented the Honorable John C. Knox, Senior Judge of the United States District Court for the Southern District of New York, from delivering his scheduled address, but an eloquent substitute address was made by Major General Chisholm, Canadian Deputy Minister of Public Health. At the final session Dr. Paul B. Dunbar, present Commissioner of Food and Drugs, offered

a motion of appreciation to the Section on Food, Drug and Cosmetic Law, for organizing this meeting. This motion was unanimously approved.

A meeting to commemorate the anniversary of this 1906 act is indicated, because it was a landmark in the social and economic progress of our country. For it was our first national food and drug law, in a basic sense; it had profound social and economic consequences, in protecting the public health and improving the food and drug order; and it led to the succeeding Federal Food, Drug, and Cosmetic Act of 1938, which is acclaimed as the strongest national law on its subject now in existence. Therefore, and because of its fundamental significance, we may say that this was the most important meeting yet held on the great law enacted by these two acts. Moreover it was a truly national meeting, for it was opened by reading a commemoration letter from the President of the United States; national leaders participated in its program; and leading national organizations were represented at it by delegation or letter, or both.

In short, this was an historic meeting to commemorate a great event in our national life, and the following record of it will have a lasting value to all interested therein.

Charles Wesley Dunn, Chairman,
Section on Food, Drug and Cosmetic
Law of New York State Bar Association

THE WHITE HOUSE
WASHINGTON

June 18, 1946

Dear Mr. Dunn:

Forty years ago, with the passage of the Food and Drugs Act of 1906, the first nationwide step was taken in defending the American people against the hazards to health and the economic consequences arising from uncontrolled mass production and manufacture of foods and medicines. That was a memorable milestone in our development through democratic processes of social legislation to meet problems that accompanied our transition from a rural to an industrial Nation.

This commemoration of the enactment of that law is evidence of the high regard in which it and its high purpose are held. It seems to me unique and noteworthy that participating in this observance will be not only representatives of the scientific, enforcement and judicial personnel concerned with its administration and the consumer groups interested in its protective aspects, but also members of the food, drug and cosmetic industries subject to its regulatory features.

Your commemorative meetings will be the occasion for paying tribute to the men and women, both in and out of Government, who pioneered the way for this legislation and those who have constantly worked toward improving our standards in food, drugs and cosmetics.

In sending greetings to you who will assemble to observe the fortieth anniversary of our first Food and Drugs Act, I should like to ask that we all consider this an occasion for rededicating ourselves to the purpose of constant improvement in the protection of the Nation's health and economic well-being through increased purity and honesty in the products which this law regulates.

Very sincerely yours,

Harry Truman

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Original Federal Food and Drugs Act of June 30, 1906 as Amended

INTRODUCTION to

Watson B. Miller, Federal Security Administrator

THE PREPARATION of this talk has been the occasion for many nostalgic memories. For it was necessary to go back more than forty years and review events that led up to the passage of the law which we are here to commemorate. The crusade for national food and drug legislation and the violent reactions to it were responsible for many front-page news stories around the turn of the century. They were the cause of much name-calling and satire and ridicule in the public press.

A lusty young nation was changing its economic complexion from agriculture to industry. The trend was toward bigger and bigger business. The whole system of food supply was following this trend. The methods of manufacture adopted were naturally the cheapest and most convenient. Some medicine manufacturers had quickly grasped the financial possibilities of selling worthless and often harmful nostrums by playing on the fears and credulity of the American people. When the movement for pure food and drugs was started, that was the national picture which I can well remember, though its details were obscure to me as they must have been to many of our citizens.

It is not difficult, however, to see how the pattern developed. Industrialization meant centralization of population. Many people who had lived on farms and in small villages and towns became concentrated in the vicinity of factories and industrial areas. No longer did the family raise most of its food and depend on the town baker or butcher or druggist—all neighbors—for its other simple needs. Distance from the source of supply made preserved and canned foods necessary. Cor-

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porations and large manufacturers took on the business of supplying food. Some of these became possessed with a craving for more and more profits at any cost to the product. Many conscientious manufacturers were put at such competitive disadvantage that they were forced to resort to practices which would permit them to meet the prices of the less ethical. It was not that human nature had suddenly deteriorated, but that distance from the customer offered new temptation to a form of cupidity. Also, in all fairness, I think we must recognize that manufacturers of that day did not have the benefit of scientific knowledge now available, and that in many instances they were not aware of the harmful nature of their products.

Debasement of Foods Aroused Public Concern

The first stirrings of public concern over the situation were directed toward the debasement of foods. This consisted chiefly of adding preservatives, artificial coloring and adulterants. Many patent preservatives were on the market which guaranteed to keep meat, fish and poultry fresh for any length of time. Canned fruits and vegetables contained both artificial coloring and preservatives. In canned, dried and smoked meats, boracic acid was a common ingredient. Substituting cheaper ingredients and selling goods under another name were common practices. Over-ripe apples were cooked and doctored with chemicals and sold as "currant," "blackberry," "plum" and other fruits. Potted chicken and potted turkey were common products, but were often found on analysis to contain no trace of chicken or turkey.

Tremendous Business of "Patent" Medicines

Even more noxious than the debasement of foods was the tremendous business developed in the sale of "patent" medicines. I well remember the quarter- and half-page ads in the newspapers that lured eager customers by the thousands and the equally fantastic labelling that prevailed. The diabolical aspect of this advertising and labelling was that it preyed on the public through the power of suggestion and fear and promised cures for everything from dandruff to tuberculosis or cancer.

Many of the panaceas contained varying degrees of harmful ingredients. Soothing syrups for babies and young children contained cocaine and morphine. "Headache powders" were often vicious habit-forming drugs. "Catarrh powders" contained cocaine.

These were some of the more flagrant evils which the public was to come to know about in time. The evils are by no means all corrected. But we have come a long way—and we owe much of our present protection from exploitation and health hazards to the courageous pioneers who fought the long battle for food and drug legislation.

Leadership of Dr. Harvey W. Wiley

I am sure the spirit of Dr. Harvey W. Wiley is with us here today. I feel very humble in trying to review for you those years and some of the events through which, with supreme devotion and zeal, he led the war on the evils of chicanery and fraud which attended the manufacture of our food and drugs. I feel particular humility in doing this; standing in the presence of Mrs. Wiley, who so well knows how much of the heart of her husband went into each phase of this sometimes heartbreaking struggle. I do ask her forbearance.

We always associate our thoughts of Dr. Wiley with the vigor, determination and indomitable spirit that were so characteristic of him. But not even all his endurance and courage could have met the forces against which he fought without moments when he was tempted to despair. Mark Sullivan, in the second volume of his series, *Our*

Times,[1] recounts an occasion on which he called at Dr. Wiley's office. Mr. Sullivan says,

> "When I opened the door of his office, he turned his head and glowering eyes toward me, looked at me silently a moment, then raised both his hands and said, 'Last night in my closet I prayed for help.' "

But such moments must have been few and quickly passing, for from first to last he led the crusade. He measured the strength of those opposing the passage of legislation and chose as his principal weapon a campaign of public education. And in the end an aroused public opinion was undoubtedly the deciding factor in success.

The doctor's name became a household word among the women of America as his stand for pure food legislation became generally known. His writings and lectures were intriguing and convincing. He inspired confidence in his views and in the unselfish purity of his crusade. In due course vigorous support was given to the cause of pure food legislation by such outstanding women's organizations as the General Federation of Women's Clubs and the National Consumers' League.

National Association of State Dairy and Food Departments Formed

While a Federal Food and Drugs Law did not come until 1906, by 1898 enough states had adopted legislation and established administrative agencies that a National Association of State Dairy and Food Departments was formed. Among the state officials were many able men who worked energetically within their states to promote the cause of a Federal pure food law. In his autobiography Dr. Wiley pays tribute to the work done by Robert M. Allen, administrator of the food laws of Kentucky, who I suspect is in the audience today. Effective work was done also by Edwin F. Ladd, State Chemist of North Dakota, and later United States Senator from that state. There were a number of others.

Propaganda at the St. Louis Exposition

The St. Louis Exposition of 1904 was the scene of an ingenious bit of propaganda which attests to the effective activities of the groups contending for pure food legislation. I am indebted to Mark Sullivan's writings for the account of this project and I shall give it to you in his words, as they appear in Volume II of his series, *Our Times*:

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[1] Published by Scribner's, New York.

"A large space had been allotted there to manufacturers of preserved foods, who put on display practically every brand and variety of canned and bottled goods manufactured in the United States. The pure-food workers, chiefly from the Association of State Food and Dairy Departments, secured from the Exposition officials permission to open a booth near by. Then the State chemists . . . set to work. They took samples of well-known artificially colored foods. From each they extracted the dye. With the extracted colors, they dyed pieces of wool and silk. To each bit of cloth they attached a properly attested chemist's certificate, explaining the nature of the dye, and giving the name of the food sample from which it had been taken. Then they shipped the whole exhibit to the pure-food booth at the St. Louis Exposition.

". . . visitors by the thousands filed by the beautifully arranged display of the food manufacturers—and then paused at the pure-food booth. Here they saw duplicated many of the cans and bottles on view in the food manufacturers' booth, each having a placard naming the deleterious substances used in its coloring and preservation. On a table, in a brilliantly hued lay-out, were the silk and woolen cloths that had been colored with dyes extracted from the foods. . . .

"The passer-by was moved to reflect that a color might be agreeable and harmless when used where it could be seen, on one of the detachable ornaments of the outer periphery of the human organism, as on a necktie, for example; but that the same color, when used on the lining of one's insides, was at best useless from the point of view of ornamentation, and at the worst might have adverse effects on one's health."

Advertisements of Patent-Medicine Manufacturers

In the early 1900's patent-medicine manufacturers were the largest national advertisers in the country. They were a source of substantial income to newspapers, large and small, clear across the nation. Their products filled the shelves of every drug store and were to be found in many small general stores.

With reference to their advertising, Dr. Wiley says in his autobiography:[2]

"Patent-medicine makers and sellers hit upon every passing whim and fancy to advertise their goods. The microbe created quite a furor in the public mind, and the nostrums glibly guaranteed to 'cure' the microbe in whatever form he might be or in whatever hiding-place this monstrous creature might be found. Germs and bacteria replaced the microbe in the public interest and 'medicines' sallied forth to attack germs and bacteria. One quack nostrum I studied carefully may be cited as an example of the whole sorry lot. The concoction was a weak solution of sulphuric and sulphurous acids, with an occasional trace of hydrochloric and hydrobromic acids, and the bulk of it was water."

Dr. Wiley then lists the thirty-seven ills which its advertisers guaranteed it would "cure" and concludes,

". . . all arranged nicely in the advertisements in alphabetical form so that your particular ill could easily be located—and, so the announcements continued, 'all dis-

[2] Published by Scribner's, New York.

eases that begin with fever, all inflammations, all catarrh, all contagious diseases, and all the results of impure or poisoned blood; in nervous diseases our remedy acts as a vitalizer, accomplishing what no drugs can do.' "

Exposure of Patent-Medicine Manufacturers

Exposure of the practices of unscrupulous patent-medicine manufacturers which probably had the most far-reaching effect was carried on by two widely read national periodicals, the *Ladies' Home Journal* and *Collier's Weekly*. Both of these magazines conducted campaigns to inform the public of the contents of the medicines which they so trustingly bought and took. The *Ladies' Home Journal* published analyses of many widely used patent medicines, some of which were found to be innocuous but worthless, others to contain dangerous drugs. Practices in advertising in which the public was played fast and loose were also publicized by these two magazines.

Early Efforts to Pass Food and Drug Legislation

Some years before these crusades, attempts had been made to get legislation through Congress. Concerning these early efforts, Dr. Wiley has this to say in his autobiography:

"In 1889 Senator A. S. Paddock, of Nebraska, introduced the first bona fide pure food bill to be considered by Congress. After a long and somewhat heated discussion before the Senate the bill passed that body, but it failed to receive the approval of the House. During the next several sessions other bills of the same character were presented in one or the other Houses of Congress, to be killed promptly, usually amid laughter and ridicule. In fact, pure food measures were smugly looked upon as the work of cranks and reformers without much business sense. . . .

. . . . . .

"The elements fighting us represented certain interests. All those who were preserving foods by means of chemicals were staunch in opposing legislation which would limit the trade practises they held to be legitimate and on which they supposed the life of their businesses depended. There were the manufacturers of articles used in the adulteration of foods, and drugs; the so-called 'rectifiers,' that is, those who made fraudulent whisky out of alcohol, colors and flavors; the patent-medicine fraternity of fraud and hokum; the dishonest misbranders and mislabelers of food and drug products; and that unnumbered host engaged in business which would be controlled or eliminated entirely by a pure food law."

Food and Drug Act of 1906

The bill which was finally enacted into law was introduced in December, 1905, by Senator Heyburn of Idaho. It passed the Senate in February, 1906, and was sent to the House committee, where it rested several months.

During these months the public concern over the food supply system was aroused to new heights by a best-selling novel, *Jungle*,[3] whose author was, you will remember, Upton Sinclair. This described the methods of handling meat in some of the packing houses. An investigation was ordered by President Roosevelt. The resulting report, which was made public, aroused public alarm over the meat situation and was instrumental in breaking down opposition to meat inspection legislation then pending in Congress, and finally to the Food and Drugs Act. This bill passed the House and was signed by the President on June 30, 1906.

Debt We Owe to Crusaders for Act

I have tried to cover only a few of the high lights of the stormy struggle that finally ended with our first Food and Drugs Act. Probably there are others here besides myself who can remember that period in our nation's history and have been taken back in memory to the days when housewives were aroused to a degree of righteous indignation that finally made itself felt in Congress. I hope I have been able to bring to life some of the spirit of the staunch crusaders on the side of pure food and drugs and to recall the great debt we owe to them.

Evils Existed More Than Forty Years Ago

The share in this meeting assigned to me was to cover factors that contributed to passage of the first Food and Drugs Act. To do this honestly, it was necessary to point out the evils in the manufacture of foods and drugs that made this legislation necessary. Fortunately, that was more than forty years ago.

Support of Food and Drug Manufacturers

I should like to take this occasion to say that as Administrator of the Federal Security Agency, of which the Food and Drug Administration is a very important part, I am very much aware of the support the great majority of the food and drug manufacturers are giving to effective administration of the law. That they are so well represented here today to participate in commemorating passage of the law is evidence of that fact.

[*The End*]

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[3] Published by Scribner's, New York.

Original Federal Food and Drugs Act of June 30, 1906 as Amended

ITS LEGISLATIVE HISTORY[1]

Charles Wesley Dunn

THE legislative history of the original Federal Food and Drugs Act of June 30, 1906, is principally found in two official records. The first is the record of action by Congress, for the law which this act eventually enacted; i.e., a national law to prohibit the adulteration or misbranding of food and drugs in interstate and foreign commerce. The second is the record of action by the United States Department of Agriculture, for the investigation of food adulteration in particular; on which this act was based and as a result of which Dr. Harvey W. Wiley led the movement for its enactment.

Therefore I will now review each such action; and in doing so I will add explanatory comments on it. The law before us will be called the 1906 act, for convenience; and the terms "food" and "drugs" will be used in their broad meaning, whereby the former also includes drink and the latter refers to medicine as well.

Part I

Action by Congress

1

The action by Congress for the national food and drug law enacted by the 1906 act is defined in the bills leading to it and in the legislative record of them. These bills numbered 103 in all.

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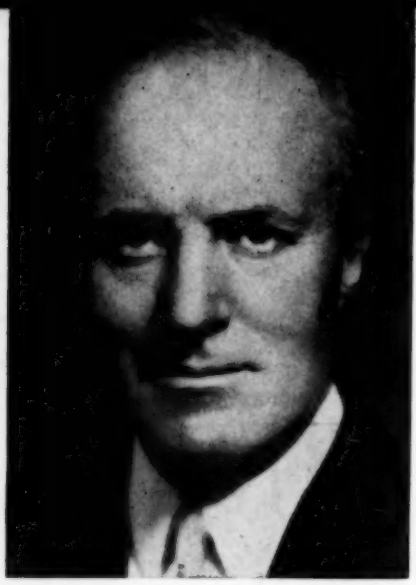
[1] Mr. Dunn expresses his appreciation to Mr. Frank T. Dierson, for his research assistance in preparing this paper.



Charles Wesley Dunn is Chairman, Section on Food, Drug and Cosmetic Law of New York State Bar Association

The first was the Edwards Bill of 1848, prohibiting the importation of adulterated drugs. The American Medical Association and the New York and Philadelphia Colleges of Pharmacy petitioned for its enactment; it became a law on June 26 in that year; and in 1890 Congress enacted a parallel food importation act through the Edmunds Bill. But the principal bills were those reaching food and dealing with a regulation of interstate commerce. Of them, the first was the Wright Bill of 1879, prohibiting the adulteration of food. It was expanded in the Hawley Bill of 1881, to prohibit the adulteration of food and drugs; and then in the Lee Bill of 1888, to prohibit the adulteration or misbranding of food and drugs, which created the pattern for the 1906 act. Hence Congressional action for this act started in 1848, exactly 58 years before it was enacted. This action got under way in 1879, or 27 years before the act became a law; and it developed its final pattern in 1888, or 18 year before that time. That is why the Edwards, Wright, Hawley and Lee Bills are called the pioneer ones for this act.

Thus it is clear that the 1906 act was over half a century in the making, from an over-all standpoint; and that its principal legislative progress was from a law against the adulteration of food to a law against the adulteration of food and drugs to a law against the adulteration or misbranding of food and drugs. This progress was an evolutionary one; and it is explained by the fact that the major legislative objective was to prevent the adulteration of food. That is why this act was officially called and is commonly known as a "pure food law." This does not mean

that a "pure drug law" is of lessor importance, but only that the legislative emphasis was primarily on a "pure food law." We may extend the foregoing explanation by adding that this act was mainly predicated on investigations into the purity of food; and that its enactment was sponsored by so-called "pure food congresses" of those concerned to have such a law.

It should be recorded here that no bill was introduced, before the 1906 act, to prohibit the false advertisement of food and drugs, or the adulteration and misbranding of cosmetics. For they had not yet become subjects of national legislation, which was eventually enacted in the succeeding Federal Food, Drug, and Cosmetic Act of 1938. We should add that prior to 1906 Congress enacted a limited act against the misbranding of food in interstate commerce, supplementing the 1848 and 1890 acts against the importation of adulterated food and drugs. It was the Sherman Act of 1902, prohibiting the false branding of food and dairy products as to the place of their origin. We should further add that in this earlier period bills were introduced to prohibit the adulteration of specific foods, including sugar, molasses, sirup, lard and baking powder, which were not enacted. But Congress did then enact numerous special food and drug laws, including those relating to tea, oleomargarine, filled cheese, mixed flour, adulterated and processed or renovated butter, meat inspection and opium; and it also enacted numerous local food and drug laws, which principally applied to the District of Columbia and require no mention at this time. This last statement invites the comment that the first food or drug law enacted by Congress was apparently the 1824 Flour Inspection Act for the County of Alexandria, in the District of Columbia. Therefore it may be said that the historical evolution of the national food and drug law was from a special law to a general one, and from a food law to a drug law to a food and drug law.

2

But of the 103 bills leading to the 1906 act, the key active ones numbered 19. For this act grew out of their legislative consideration in committee and on the floor; and the leading bills in this decisive class numbered seven. They were: (*1*) the Beale Bill of 1880, prohibiting the adulteration of food, because it was the first such bill favorably reported by committee; (*2*) the Flower Bill of 1882, prohibiting the adulter-

ation of food and drugs, for the same reason; (*3*) the Lee Bill of 1888, prohibiting the adulteration or misbranding of food and drugs, for the same reason; (*4*) the Paddock Bill of 1891, containing that broad prohibition, because it was the first bill to pass a branch of Congress in 1892; (*5*) the Hepburn Bill of 1901, containing the same broad prohibition, because it was the second bill to pass a branch of Congress in 1902; (*6*) the Hepburn Bill of 1903, containing the same broad prohibition, because it was the third bill to pass a branch of Congress in 1904; and (*7*) the Heyburn Bill of 1905, containing the same broad prohibition, because it was the bill which finally passed both branches of Congress and was enacted into the 1906 act. Analysis of these bills discloses two facts. One is that Congress actively spent over a quarter of a century in enacting this act. The other is that its law nearly reached the statute books in 1892, or 14 years earlier; in 1902, or 4 years earlier; and in 1904, or 2 years earlier.

If, however, we take all the 19 key bills into consideration their legislative history of the 1906 act may be divided into four periods and broadly explained as follows.

First Period: This period extended from 1880 to 1890, or for a decade. During it seven bills were reported from committee. They were: the Beale Bill of 1880, the Flower Bill of 1882, the McComas Bill of 1886, the Green Bill of 1886, the Frederick Bill of 1886, the Lee Bill of 1888, and the Faulkner Bill of 1889. They invite four significant comments. The first comment is that the Lee Bill of 1888 was the first broad one against the adulteration or misbranding of food and drugs, as previously indicated, which created the pattern for the subsequent bills and the 1906 act. The second comment is that the three 1886 bills were each adversely reported from committee on the ground that such legislation was unconstitutional and for state enactment instead, as a matter of public policy. This objection is explained by the narrow view of Congressional power over commerce and by the strength of the "state's rights" doctrine at that time; it suffices now to say that no bill leading to the 1906 act was thereafter adversely reported on the aforesaid ground. The third comment is that all these bills, except one, arose in the House, which is the branch of Congress closer to the people. Hence it may be said that this act originally sprang directly from them. The fourth comment is that the most important bill in this group was the

original broad Lee Bill, which was favorably reported from committee; but Congress did no more about it. In short: in this period the legislative movement for a national food and drug law started in the House; it first questioned the validity of this law; it then favorably reported a broad bill therefor; but it did nothing more to enact such a law.

Second Period: This period extended from 1890 to 1900, or for another decade. During it five additional bills were reported from committee. Each contained a broad prohibition against the adulteration or misbranding of food and drugs; and each was favorably reported, with an unimportant exception. These bills were: the Paddock Bill of 1890, the Paddock Bill of 1891, the Edmunds Bill of 1892, the Hatch Bill of 1893, and the Faulkner Bill of 1898. They invite three significant comments. The first comment is that they were largely and principally Senate bills; which is a reverse of the legislative situation in the first period. The second comment is that the Paddock Bill of 1891 was the dominating one. It passed the Senate on March 9, 1892, without a dissenting vote, and was the first bill to pass a branch of Congress. It was promptly, unanimously and favorably reported in the House; but the latter then failed to complete its enactment. The third comment is that all these bills were reported by the Agriculture Committees, which then exclusively dealt with the active bills; and it should be added that the major Lee and Faulkner Bills in the first period were likewise reported by them. In short: in this second period there were fewer active bills, but they were more important. The initiative for their law then passed from the House to the Senate; and it was the House which blocked the enactment of this law.

Third Period: This period extended from 1900 to 1905, or for half a decade. During it six additional bills were reported from committee. Each contained the same broad prohibition against the adulteration or misbranding of food and drugs, except one; and each was likewise favorably reported. These bills were the Mason Bill of 1900, the Brosius Bill of 1900, the Hepburn Bill of 1901, the Hansbrough Bill of 1902, the McCumber Bill of 1903, and the Hepburn Bill of 1903. And they invite four significant comments. The first comment is that they were principally House bills; and therefore the initiative for their law then reverted from the Senate to the House, where it started. The second comment is that the Hepburn Bills of 1901 and 1903 were the dominating

ones, in this period; both arose in the House. For the first Hepburn Bill passed the House on December 19, 1902, by a 71 to 22 vote, and was the second bill to pass a branch of Congress; it was promptly and favorably reported in the Senate; it was then debated in the Senate; but it did not reach a final vote there. As to the second Hepburn Bill, it had a parallel career. For it passed the House on January 20, 1904, by a 201 to 68 vote, and was the third bill to pass a branch of Congress; it was promptly and favorably reported in the Senate; the Senate debated it; but it likewise did not reach a final vote there. The third comment is that in this period the Senate Manufactures Committee and the House Interstate and Foreign Commerce Committee took charge of such legislation, replacing the Agriculture Committees; and eventually secured its final enactment in the 1906 act. The fourth comment is that the Mason Bill of 1900 was the exceptional limited one, because it was confined to the adulteration of food; and therefore it was an outmoded throwback to the original bills for a restricted law. In short: in this third period the number of bills was nearly the same as in the preceding one; but they were still more important, because they made greater legislative progress. Furthermore the House then resumed its leadership in such legislation; and the Senate now blocked its enactment.

Fourth Period: This period extended from 1905 to the enactment of the 1906 act; and it was the period of the final drive to secure this act. Only one additional bill was then favorably reported from committee; and it contained the same broad prohibition against the adulteration or misbranding of food and drugs. This was the Heyburn Bill of 1905, which arose in the Senate. It passed the Senate on February 21, 1906, by a 63 to 4 vote; it passed the House on June 23, by a 241 to 17 vote; and it became a law on June 30, on its approval by President Theodore Roosevelt. He had recommended its enactment in his annual message to Congress on December 5, 1905; and this was the first Presidential recommendation of such legislation, up to that time. We note here the historical coincidence that it was the second President Roosevelt who recommended and approved the enactment of the succeeding 1938 act. In short: in this last period public opinion for a national food and drug law had become so strong that it was finally enacted by an overwhelming vote in each branch of Congress; and each branch was equally responsible for its enactment. For the House Committee substituted the perfected Hepburn Bill for the Senate Heyburn Bill, and the enacted act was a

combination of both. And while the latter bill was the first to carry the name of Senator Heyburn, he had long been active in promoting legislation for the law it enacted.

3

We have now completed this review of the legislative history of the 1906 act from the standpoint of Congressional action therefor; it should be followed by a statement of the basic reasons why this law was enacted. But before considering them we will add two general observations.

The first observation is that the great names in the foregoing history are: Representatives Edwards of Ohio, Wright of Pennsylvania, Beale of Virginia and Lee of that state, who were outstanding pioneers in this legislation; Senators Faulkner of West Virginia, Mason of Illinois, McCumber of North Dakota and Hansbrough of the same state, and Representatives Hatch of Missouri and Brosius of Pennsylvania, who were prominent in its intermediate development; Senator Paddock of Nebraska and Representative Hepburn of Iowa, who nearly secured its earlier enactment; and Senator Heyburn of Idaho and Representative Mann of Illinois, who sponsored its final enactment. These leaders in Congress for a national food and drug law are named to pay them due tribute; to note that they principally came from agricultural states; and to record the fact that representatives of agriculture were foremost advocates of this law, because they were deeply concerned that agricultural products sold to the consuming public should be pure, wholesome and honest. Furthermore, it was the agricultural committees in Congress which exclusively handled the bills for this law, from 1890 to 1900; it was the Department of Agriculture which made the investigations of food adulteration, in particular, on which this law was based; and it was Dr. Wiley in that Department who led the national movement for the enactment of this law.

The second observation is the supplemental one that the responsible organizations of the food and drug industries and trades appropriately supported the enactment of this law from the beginning to the end of its legislative career. This fact is established by the recorded petitions and official reports for such a law. For example: the first petitions to Con-

gress in 1881 were principally by Boards of Trade and Chambers of Commerce. The early 1900 report on the Brosius Bill said:

"This measure is endorsed by the following great organizations of the country: American Chemical Association, American Medical Society, American Bee-Keepers Association, American Pomological Society, American Pharmaceutical Society, Association of American Colleges and Experiment Stations, Association of Dairy and Food Commissioners, Association of Agricultural Chemists, National Confectioners, National Board of Trade, National Grange, National Alliance and Industrial Union, National Retail Grocers' Association, National Millers' Executive Committee, National Pure Food Association, National Preservers and Syrup Refiners Association, National Retail Liquor Dealers' Association, Proprietary Association of America, Society of Vital Friends, United States Brewers Association, Universal Peace Union, Women's Christian Temperance Union, Wholesale Druggists Association. In addition to these, State granges, State Alliances, State boards of agriculture, horticultural societies, and local organizations of grocers, pharmacists, scientists, boards of trade, physicians, and chemists are to be found among those who have petitioned for the passage of this bill, and practically the whole press of this country have urged the necessity of thus regulating the health, morals, and business of the country."

We may add that it was the confectioners who promoted the original state laws against the adulteration of candy, and that it was the druggists who promoted the original state laws against the adulteration of drugs. We should go on to say that the national wholesale and retail drug and grocery organizations were original and constant supporters of the law eventually enacted by the 1906 act.

4

With these observations we now come to a statement of the basic reasons why the 1906 act was enacted. They are at least three in number.

The first is the manifest reason that a national law against the adulteration or misbranding of food and drugs was required to protect the public health and to secure fair trade in commerce. There is no question about the actual need of this law, because it was established through authoritative investigations by Congress and the Department of Agriculture. The investigations by the Department are later described; and the investigations by Congress were directed by resolution or made in a long series of committee hearings on active bills for such a law.

We should add here that Congress instituted action to investigate food and drug adulteration for a national law against it, as early as 1881, or shortly after the pioneer Wright Bill of 1879. For then a House committee favorably reported the Young Bill, authorizing an investiga-

tion of food adulteration; which was not enacted. Thereafter, in 1884, a House committee favorably reported the Green Resolution, directing an investigation of food and drug adulteration for legislation against it; which was defeated on the ground that such legislation is unconstitutional and a matter for a state enactment instead. This objection we have previously noted; it was again reflected by the Morgan Resolution of 1888, directing the Senate Judiciary Committee to report whether Congress had the power to enact legislation for the prohibition of food adulteration within a state; on which no action was taken. An investigation of food and drug adulteration was again unsuccessfully sought through the Taylor Resolution of 1886 and the Thurston Bill of 1899. But in 1898 the Senate agreed to the Cannon and Mason Resolutions, which directed the Senate Manufactures Committee to investigate food adulteration; this investigation was a notable one; the report on it was filed in 1900. Furthermore, the Perkins Resolution of 1900 was also agreed to, which directed the United States Industrial Commission to make a report on its investigation of food adulteration, etc.; it was filed in 1901. And from 1900 on, resolutions were agreed to for reports on existing food and drug laws.

In thus speaking of the need for a national food and drug law, we should go on to say that during the quarter of a century when the 1906 act was legislatively developed, our country was emerging from a rural into an industrial nation; the food and drug industries were beginning to be organized on the basis of mass production and distribution; the science of food and drug manufacture had reached the point where it could be constructively used to improve these products or destructively used to debase them; and the uncontrolled forces of competition were working for the sophistication of these products, in order to secure the commercial advantage of a lower price. All of which means that the inherent need for the law of this act was then progressively increased by the evolution in the food and drug order and a working of the forces underlying its competitive operation.

The second basic reason for the enactment of the 1906 act was the otherwise limited action by the states to prevent the adulteration or misbranding of foods and drugs. This limitation on their action to do so may be explained as follows. In the first place, some states had failed to enact adequate food and drug legislation, because there was no

national standard or incentive for it. In the second place, some states did not sufficiently administer this legislation, which they had enacted, for want of adequate appropriation or organization or because of some other reason. In the third place, the legal ability of a state to regulate food and drugs introduced from another state was impaired by the so-called "original package" doctrine of constitutional law, laid down by the Supreme Court. And in the fourth place, it was constitutionally argued before the 1906 act was enacted that the absence of a national food and drug law by Congress was a binding notice to the states that interstate commerce in these products should be free of regulation by them.

The third basic reason for the enactment of the 1906 act is that it was essential to secure a uniform law against the adulteration or misbranding of food and drugs, throughout the country. Such a law is necessary to provide our people with equal protection against this manipulation of such products, and to ordain a single rule of commerce for them. This comment has the force of the fact that when the 1906 act was enacted the state food and drug laws were in an irreconcilable condition of divergent and conflicting provisions, e.g., with respect to food standards; and that after its enactment they achieved a large degree of uniformity, much more indeed than that which has followed the enactment of the succeeding 1938 act. This situation is explained by the further fact that the greater severity of the latter act has invited more resistance to its state duplication; and that such act has been effective for a much shorter time. Furthermore, there still exists a Yankee independence of state legislation, and a "state's rights" insistence on the enactment of one's own legislation.

5

In view of these conclusive reasons for the 1906 act, we should next consider why Congress did not enact it sooner. This question should be approached from the standpoint that Congress actively spent more than a quarter of a century in enacting it. But an examination of the basic causes for the delay in this act and of the immediate interferences with its earlier enactment rationally explain the situation thus presented, however much we regret it.

As to the basic causes for the delay in this act: in the first place, the quarter of a century preceding its enactment was an era in our national life when Congress was first beginning to enact legislation for a broad regulation of commerce, which started with the Interstate Commerce Act of 1887. Therefore the concept of such legislation was then new; and its enactment could not go faster than at a slow evolutionary pace, under normal conditions. In the second place, this was a period in which the traditional doctrine of "state's rights" was strongly entrenched throughout the country and especially in the South; and a great number of our people sincerely challenged any Federal law to regulate the ordinary affairs of life, on the ground that this was exclusively a subject for state regulation (if any) as a matter of public policy. In short: the present policy of a broad national regulation of these affairs, in basic respects, was then virtually nonexistent; any advocacy of it produced immediate and violent opposition. And in the third place, the constitutional power of Congress to regulate commerce was then given a narrow construction, and there was a long line of decisions by the United States Supreme Court to sustain it. As a result, it was responsibly and widely argued that a Federal law against adulteration or misbranding of food and drugs was virtually a regulation of their manufacture within a state, and therefore an invalid police measure. This was the argument made to support the adverse report on the 1886 bills for the law of the 1906 act, which has been noted; and it was the argument made in the minority reports on subsequent bills for this act, right up to the time of its enactment. To be sure this was a minority argument, but it had sufficient influence to delay the enactment of such act. And we should add that this conception of Congressional power to regulate commerce has now gone to the other extreme. For example: a seizure proceeding under the Federal Food, Drug, and Cosmetic Act of 1938 expressly reaches a product at any time after it enters interstate commerce; the Supreme Court has construed the Sherman Antitrust Act to reach a conspiracy in undue restraint of intrastate commerce; and our highest court has construed the Fair Labor Standards Act to reach maintenance employees in a building from which production for interstate commerce is managed.

As to the immediate interferences with an earlier enactment of the 1906 act, it suffices now to mention three. The first interference was that this act enacted a national food and drug law, which was new

and experimental legislation; with the result that its provisions were highly controversial. Hence there was a great divergence of honest opinion about its form, which was accentuated by the conflicting condition of the state food and drug laws. In this situation it was very difficult to find a common ground for the development of such a law. The second interference was a long and uncompromising difference of opinion between the House and Senate over major provisions in this law, and the consequence was that when one branch passed a bill for it the other invariably substituted a different bill. For example, the House long insisted on a provision authorizing the administrative establishment of food standards, whereas the Senate refused to approve such a provision and won out. We should add that there was no controversy over a provision authorizing United States Pharmacopœia standards for drugs; and the only concern about it was to add a variation clause for its validity, which Dr. James H. Beale originated. Again, the Senate long insisted that a new agency be created in the Department of Agriculture, to administer this law; whereas the House insisted that it be administered by the established Bureau of Chemistry headed by Dr. Wiley, and won out. The third interference was a composite of miscellaneous objections to this law. They included the objection of a minority group to its enactment at all; the objection by some to its administration by Dr. Wiley, because he was feared and as a result there was an unsuccessful attempt to vest its administration in the Secretary of Commerce; the objection arising from the bitter controversies over what is whiskey and whether certain baking powders are unwholesome; and the general objection of those who opposed any such law, on the ground that it is sumptuary or paternalistic legislation or that it imposes a bureaucratic control of business, which would set loose "a pestilential lot of spies, meddlers and informers."

But it serves no useful purpose to press our examination of this situation further. For in the course of time the legislative problem involved in developing a national food and drug law was duly solved. The 1906 act was enacted by an overwhelming vote of Congress—a vote which clearly reflected the conscience of our people, and expressed their will to have this protective legislation, without further ado.

Part II

Action by Department of Agriculture

6

Let us now turn to the action by the United States Department of Agriculture in the legislative history of the 1906 act. It involved the investigation of food and drug adulteration, on which this act was based, and the decisive recommendation for its enactment. In reviewing such action we will show that Dr. Harvey W. Wiley was the founder of this act.

For many years there was a Division of Chemistry in that Department, which became the Bureau of Chemistry in 1901. This Division and later the Bureau made scientific analyses and studies of agricultural soils, fertilizers and products, which were extended into the field of food and drugs. They were authorized by the annual agricultural appropriation acts. From 1863 to 1879 the Chief Chemists of this Division were Messrs. Wetherell, Erni, Antisell, Brown and McMurtrie, who annually reported routine agricultural action, except that there was a reference to an analysis of pharmaceutical preparations in 1869. But in 1879 the Division began an investigation of food and drug adulteration, when Mr. Peter Collier became Chief Chemist of it; which coincided with the introduction of the pioneer Wright Bill. And in his 1880 report Mr. Collier recommended the enactment of a national food and drug law. For he then said:

"* * * the law there (in England) makes it a misdemeanor to sell any article of food, drink, or medicine under any false or misleading name. A law, carefully framed, is greatly needed in this country, where adulteration and substitution are every day practiced."

Again:

"Laws should be made and vigorously enforced making the adulteration of foods and medicines a criminal offense. Where life and health are at stake no specious arguments should prevent the speedy punishment of those unscrupulous men who are willing, for the sake of gain, to endanger the health of unsuspecting purchasers."

Therefore Mr. Collier must be given the credit for making the original recommendation of such a law by the Department, which was eventually enacted in the 1906 act.

The action thus instituted by Mr. Collier for an investigation and the prevention of food and drug adulteration was broadly expanded and successfully completed by Dr. Wiley, who became head of the Division of Chemistry in 1883; and then chief of the Bureau of Chemistry in 1901 until his resignation in 1912. He immediately began a long, authoritative and historic series of food adulteration investigations by the Division and Bureau, which developed into their major action, and the results of which were published in bulletins of great public value. In 1888 President Cleveland characterized their publication as

"the most complete treatise on that subject that has ever been published in any country;"

and in 1892 the Secretary of Agriculture said that

"the amount of chemical work which has been done (by the Division) on this subject is perhaps the largest of any similar chemical work anywhere in the history of science."

It should be added that the publication of these scientific bulletins was supplemented by additional ones on the history of food adulteration, and on the laws against food and drug adulteration.

We should go on to say that these investigations included a basic study of the addition of preservatives, colors and other substances to food, for a determination of their dietary and any harmful effect, in which the so-called "poison squad" was used; a basic study of the nutritional value of specific foods; and a basic study of methods to analyze foods and determine their adulteration, made in collaboration with the Association of Official Agricultural Chemists. These studies marked significant progress in the science of food and nutrition. Furthermore such investigations involved the establishment of standards of identity for common foods, in collaboration with the aforesaid Association, and in due course they were extended to drug adulteration, primarily to disclose habit-forming and other harmful medicines and those which were a fraud. To make these investigations more effective a Food Laboratory was created in 1902, under Dr. W. D. Bigelow, and a parallel Drug Laboratory, in 1903.

This historic series of investigations directed by Dr. Wiley clearly proved the need for a broad national law against the adulteration or

misbranding of food and drugs; as a direct consequence of them this law was finally enacted in the 1906 act. Dr. Wiley repeatedly recommended such a law in his annual reports. For example, in the 1898 report he said:

"The necessity of national legislation on this subject has long been apparent, for it is evident that State laws, however excellent and well executed, cannot realize their full purpose without the supplement of federal legislation."

This reference to state food and drug laws invites the comment that Dr. Wiley's investigations also stimulated their enactment. In addition, Dr. Wiley in effect directed the notable investigation of food adulteration by the Senate Manufactures Committee, which was previously noted. In his 1900 report he said: "The results of the activities of the Division in this direction were largely instrumental in securing the introduction of a pure-food bill into Congress * * * and its favorable consideration" by the House and Senate committees. After he had proven the need for such a national law, Dr. Wiley instituted and led a national crusade for it, which he conducted with brilliant ability and indefatigable effort. In doing so he organized national pure-food congresses to promote this law, and he thus and otherwise developed a public opinion which eventually forced its enactment by an overwhelming vote. Furthermore he was the principal adviser of Congress in its development of the 1906 act and the dominating draftsman of it. This is why Representative Mann said on the floor of Congress on June 29, 1906, after the House had agreed to the conference report for this act:

"I have constantly sought his advice as well as his knowledge of the facts. We owe much to him."

Finally, it was Dr. Wiley who originally administered the 1906 act until he resigned in 1912, acting under the Secretary of Agriculture; and the record of his administration of it is that of a fundamental public service.

8

This in brief is the story of the leading part which Dr. Harvey W. Wiley played in the legislative history of the 1906 act. This act truly carries his name; it will be known for all time as the "Wiley Pure Food and Drug Law"; and as a result he will have a deserved place in the

history of our country. We suggest that the magnificent bronze bust of him made by Gutzon Borglum be given an appropriate official place in Washington. In the making of the bust this famous sculptor said that Dr. Wiley had "the greatest face since Lincoln's."

In short, it is the story of a great American who was principally responsible for our original national food and drug law, and was the founder of the 1906 act, which created it. Therefore we reverently honor the memory of Dr. Wiley at this historic meeting to commemorate the fortieth anniversary of that act.

Part III

In Conclusion

Notwithstanding that Congress actively spent more than a quarter of a century in enacting the 1906 act, it was not a perfect national food and drug law; it contained material defects of commission and omission. But there is no occasion for surprise over this situation, because the law thus enacted was new, experimental, and highly controversial legislation; it was practically necessary to make some compromises to secure its enactment at all; and its perfection was an evolutionary development, in the long and broad view. The surprise is rather that this act was such a strong law in essential provisions; and the decisive consideration is that it was a good beginning in a national food and drug law, which Congress could and did later perfect. Furthermore this act was drawn in accordance with the American tradition of prohibiting wrongful conduct in business and otherwise leaving it free; it had the great historic significance that prior to its enactment our country was backward in such a law, whereas after its enactment we became a world leader therein.

When the House completed its enactment of the 1906 act, on June 29 in that year, Representative Mann made this final comment on the floor:

"Mr. Speaker, in my opinion the pure food bill, which will surely become a law, is a distinct step forward, and I believe it will prove itself to be one of the most valuable and most popular laws ever placed upon the statute books."

That phrophecy was justified, and it has been realized. This act was indeed a most valuable one, because it contained basic prohibitions of food and drug adulteration, which intimately touched and benefited our people in their daily lives, as no other Federal law did. Moreover, it was well administered by Dr. Wiley, Mr. R. E. Doolittle, Dr. Carl L. Alsberg, Mr. Walter G. Campbell and their associates, who included the present able Commissioner of Food and Drugs, Dr. Paul B. Dunbar. For these and other reasons this act had profound social and economic consequences for protection of public health and improvement in the food and drug order; and, in addition, it led to the succeeding Federal Food, Drug, and Cosmetic Act of 1938, acclaimed as the strongest national law on its subject in existence.

Now, if all this is so, it is correctly said that the 1906 act was an historic landmark in the social and economic progress of our country.

[*The End*]

CONGRESSIONAL DEBATE ON THE 1938 ACT

"Mr. Lea . . . Mr. Chairman, the bill before us is what might be termed an evolution of the Wiley Act of 1906, which bears the name of Dr. Wiley because of his great service in behalf of public health in the United States. That was 32 years ago. Since then there have been very few amendments to the Food and Drug Act. There has been a revolution in the United States so far as the preparation of food is concerned. In 1906 the home was the laboratory and the place of preparation of food for the American people. That was true almost entirely. Today a large proportion of all the foods consumed by our people is prepared in the factories of the United States.

"In this same period of 32 years we have witnessed the development of the germ theory of disease. While it was known in 1906, the full ramifications and importance of the germ theory as a source of disease has largely developed since that time." House Debate, 83 Congressional Record, May 31, 1938.

Original Federal Food and Drugs
Act of June 30, 1906
as Amended

.....ITS GREAT FOUNDER

I WANT TO BEGIN THIS TRIBUTE by expressing appreciation to the Section on the Food, Drug, and Cosmetic Law of the New York Bar Association, for inviting me to be its guest on the historic occasion of the fortieth anniversary of the signing of the "Pure Food Law," which also is the sixteenth anniversary of the death of the "Father of the Law," Doctor Harvey W. Wiley. During these sixteen years it has been my singular privilege to launch a Victory Ship, the *Harvey W. Wiley*, at the yards of the California Ship Building Company, Los Angeles, California, October 15, 1943; to take part in the hundredth anniversary of Dr. Wiley's birth, celebrated by the Division of Agricultural and Food Chemistry of the American Chemical Society on the evening of September 12, 1944, at the Commodore Hotel, New York City; and to be present at a commemorative meeting of the Association of Official Agricultural Chemists honoring Dr. Wiley. All these occasions have been a rare privilege to one who, having shared a portion of his earthly career, believes that he was worthy of the honors paid him.

Dr. Wiley's Life Is a Tale of Love, Veneration, Devotion and Hard Labor

Dr. Wiley's life is a tale of love and veneration to his parents, devotion to his home, and, during his boyhood and early manhood, one of heavy manual labor. His success was due to his never-ending industry through a long life, to his deep sense of humor, and because of consecration to an ideal which ended in victory. "Don't slow up as you

Anna
Kelton
Wiley

grow older," he used to say. "Speed up, or you are apt to get stiff in the joints. Rest is the most dangerous threat to old age."

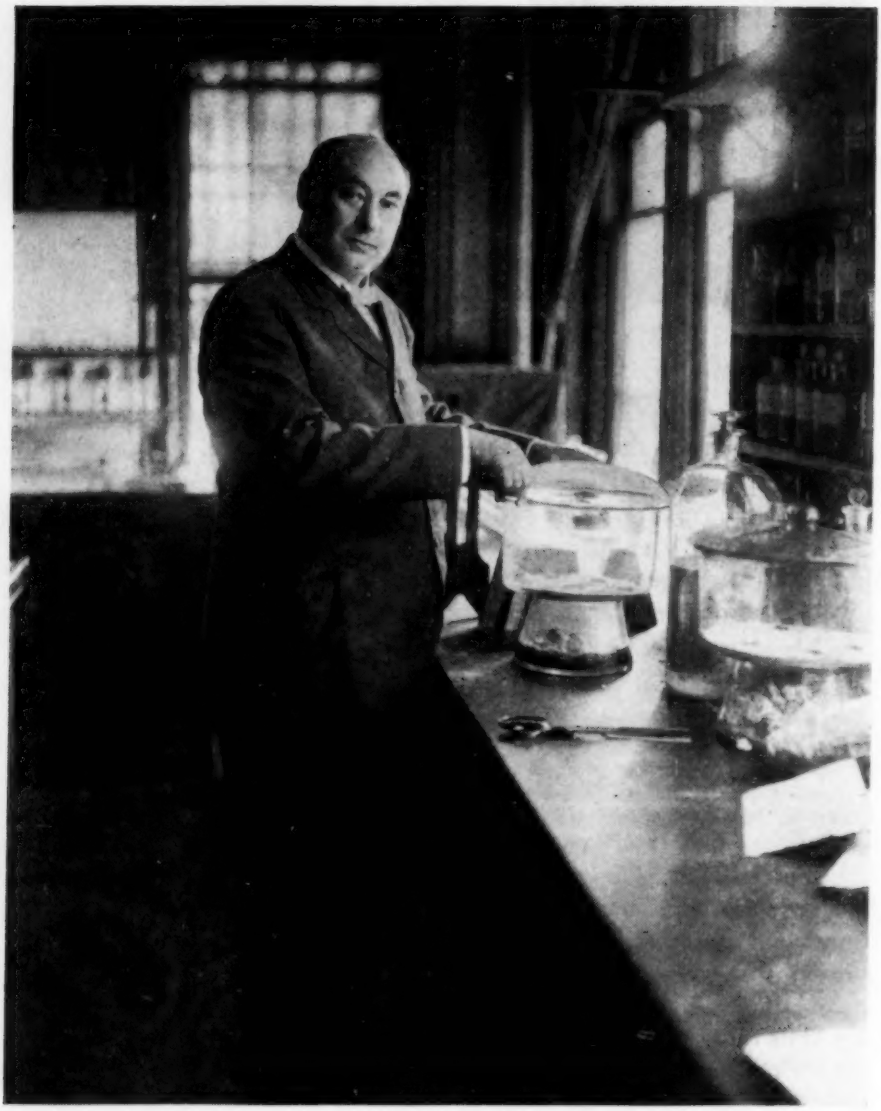
His Early Life

Dr. Wiley was born in the year 1844, in Kent, Jefferson County, Indiana. His parents, who were of pioneer stock, arrived at that place by flat boat on the Ohio River. In his biography,[1] he says:

"My ancestors dealt with the forces of Nature and struggled to create order and prosperity from the rough setting in which Fate and the times placed them. I have dealt with the *forces of human nature* and I like to believe that I have struggled to set up standards of justice and right. Stern Nature fights back at the pioneer and strives mightily at first to stay the hand that would plant gardens where none grew before. But Time finally joins hands with the pioneer. So my life work has been a storm center of conflict, but I have lived to see the ideas for which I fought become a part of the guiding principles in the great economic structure and business systems that nourish America's millions to protect their health and well-being."

Dr. Wiley had a meagre education as a boy. In those days they had subscription schools, only lasting around three months each winter. Often too, these schools were too far away for small children to go through the snow, the mud and over swollen streams. He had in all, before entering Hanover College, Indiana, four short winters of schooling. His father, who was a farmer, was an austere man. He was learned for the times. He taught all his children both Latin and Greek. Around their fire-side during the evenings he read aloud to them the Bible, Shakespeare and the *Atlantic Monthly*, in which *Uncle Tom's Cabin* appeared as a serial.

[1] Published by Bobbs Merrill.



". . . a certain lad he had in hand some forty years ago,—named WILEY."

Matriculation at Hanover College

In the year 1863, at the age of 19, Dr. Wiley told his father that he was going to Hanover College, five miles away from the farm. His father said: "Very well, my son, go along." And so on April 9, dressed in plain homespun, grown, spun, woven and tailored on the farm by his mother, in rough cowhide shoes made by the village shoemaker, and with no baggage but his ambition, Dr. Wiley started across the fields to Hanover. He did not know a soul in the village. His heart failed him as the village came into sight. He sat down under a maple tree and argued the matter with himself. He was two people, the rough farm boy and the young man who longed to become a physician. The farm boy and the future physician argued the matter and finally both voted that he go ahead and launch upon a college career.

This human incident I saw enacted on the campus of Hanover College in 1927, when we went back for the hundredth anniversary of Hanover College and witnessed a pageant of the 100 years of its history. Dr. Wiley, at the age of 83, sitting in the front row, saw himself in the guise of a boy dressed in homespun, rough cowhide boots and funny bowler hat, arguing out his own fate, 64 years previously, as one of the episodes in the pageant.

As Dr. Wiley's father was too poor to pay his son's board, he hired an empty room and then, hitching up a wagon, he drove over to Hanover with a bed, stove and a few other articles, together with firewood and from then on, for four years, my husband lived bachelor fashion, cooking his own meals. Every Saturday he walked home for breakfast, did a full day's work on the farm, for which he received a dollar, and this dollar paid his rent for the following week. During the summers he worked on the farm for which he received enough money to buy his clothing and the necessary books. Thus he secured his education by barter, exchanging the work of his hands in manual labor for the right to be taught.

His Service in Sherman's Army

The latter part of his freshman year and nearly the whole of his sophomore year were occupied by his service in Sherman's Army. He managed however, to keep abreast of his classes and in June, 1867, received his degree of A. B., authorizing him to enter the community of educated men.

Degree of Doctor of Medicine in 1872

To raise the necessary funds to pursue his professional studies as doctor of medicine, he taught Latin and Greek at what is now Butler College, Indianapolis, also entering immediately as a student at the first session of the Indiana Medical College established by the State University in Indianapolis. In the fourth year he taught Science at the Indianapolis Central High School. In 1872 he received his diploma as a Doctor of Medicine, having also received his M. A. in 1870.

Period at Harvard

Not long after that Dr. Wiley was surprised to receive an invitation to teach chemistry in the Indiana Medical College from which he had just graduated. He felt, however, not sufficiently trained and so asked for a year's leave of absence to prepare himself. He then set out for Harvard, the college of his dreams, of which he had heard as a boy when his father read aloud from the *Atlantic Monthly*. He studied at Harvard University under Dr. Josiah Parsons Cooke, and his assistant, Dr. Charles Edward Munroe, who later lived in Washington and also taught chemistry to me when I was a student at Columbian College, of George Washington University, twenty years later.

Poem by Dr. Herbert Putnam

I must interrupt this narrative to mention a poem composed by Dr. Herbert Putnam, Librarian of Congress, in honor of Dr. Charles Edward Munroe, at a banquet at the Cosmos Club, February 21, 1912, entitled "A Token to Wiley." It begins:

> "The proudest of the laurels that a pedagogue can show
> Is a pupil whom his birch has taught the way to go;
> And the program of a dinner in honor of Munroe
> Would not suffice unless it told a few things that we know
> Of a certain lad he had in hand some forty years ago,
> Named—WILEY."

and the last two stanzas read:

> "There ne'er was necromancer quite so versatile as he
> Not Daniel, Paracelsus, or the late lamented Dee
> In the rules of sublimation, distillation and the rest:
> And who'll deny white magic in the art which can deceive
> Conspiracies with sober mien, and laughter up its sleeve?
> Or who dares say the Blarney Stone is not the Alkahest?

"So honor now the master in the pupil he's 'professed',
And drink pure health to Wiley and bespeak him of the Best,
And remember how his Maker, when he paused awhile (to rest)
Soliloquized 'I never spake a TRUER word in jest
Than — *WILEY!*'"

Degree from Harvard

To go back to the narrative, in April, 1873, Dr. Munroe suggested that Dr. Wiley try for a degree at Harvard. My husband had never dreamed of that. He had gone for a special course only and had not thought at all of taking a degree. However he made application. His petition was granted. To secure the degree he was put through a 17-day examination. First, he took the entrance examinations to the Freshman Class, then the Sophomore Class examination, then the Junior and finally the Senior. He passed them all and on June 25, 1873, he was given the degree of Bachelor of Science. He had actually been a student at Harvard a little over 5 months. John Hix, in the *Washington Post*, under the title "Strange as It Seems," has twice related this incident, with Dr. Wiley's picture and the statement that "Dr. Wiley attended Harvard College for five months and graduated with a B. S. degree." The Harvard Class of 1873 adopted Dr. Wiley as a member. He never missed a meeting of the Washington Harvard Club, and I had the pleasure of attending the fiftieth reunion of that class with my husband, in 1923, when we drove with the two boys up to Cambridge and spent the week there.

Professor of Chemistry at Purdue University

When Dr. Wiley returned to Indiana he taught chemistry at Butler College as well as at the Indiana Medical College, teaching at one in the morning, and the other in the afternoon. In August, 1874, Dr. Wiley was asked to become Professor of Chemistry at Purdue University. He thus became a member of its first faculty. In 1878 he went to Berlin to complete his studies in chemistry. There he was attached to the Imperial Board of Health under Dr. Sell and began his life work of the study of food adulteration and there lost all desire of ever becoming a physician.

His Marriage

The rest of his life story will be told by others. I have tried to indicate the rugged preparation he had for the difficult struggle which

persisted throughout his life. To be a bit personal, which after all is what life is made up of, I first met Dr. Wiley in 1898 when I joined the staff of the Library of the Department of Agriculture, at the age of 21. When he needed a stenographer I was transferred to the Bureau of Chemistry. In 1900, when he asked me to marry him (I was then 23 and he 56) he seemed too old. I declined and transferred to the Library of Congress. Ten years later, during all of which time we never met, I took up the study of law at night, and one evening, passing the Cosmos Club, Dr. Wiley boarded the street car and asked to call. In a short time we were engaged, as he did not seem old to me then at all. After that life was never dull!

Charges Against Dr. Wiley

We were married and spent our honeymoon at an important food trial, in Chattanooga, Tennessee. That summer charges were filed against Dr. Wiley, by his enemies, for allegedly paying too much to one of his consultants. Dr. W. D. Bigelow brought the papers of accusation down to the farm. When he approached the farm house, Dr. Wiley noticing that his face was white and drawn, said, "Bigelow, have you got cholera morbus?" When Dr. Wiley learned what the package which Dr. Bigelow brought contained, he waved the papers around his head three times, crying, *"Victory, Victory, Victory!"*

Representative Ralph W. Moss, of Indiana, Chairman of the Committee on Expenditures of the Department of Agriculture, came to Dr. Wiley's rescue. Representative Moss, a graduate of Purdue, and imbued with the importance of scientific agriculture, did not know Dr. Wiley. He came to Dr. Wiley's rescue solely from a sense of duty. He wrote the Resolution which authorized his Committee to investigate the charges. He was a farmer, not a lawyer, but he conducted the hearings with consummate skill. Dr. Wiley was gloriously vindicated and what was more, his ideas on food adulteration were spread far and wide throughout the country. The H. J. Heinz Company sent us a large packing box full of clippings about the trial, which I have to this day.

Associate Editor, Good Housekeeping Magazine

After his vindication in April, 1912, Dr. Wiley believed that he could be of more service to the people free from the trammels of the Bureau of Chemistry. Many offers were made to him for positions

outside the government, but he chose to become associate editor of *Good Housekeeping Magazine*, which post he held until the time of his death.

At the age of 66 Dr. Wiley thus began a new career, at an age when most men cease in their labors. He married, had two sons, wrote seven books, bought the farm and spent five summers on the Chautauqua circuit. His work for the magazine was heavy as it required the constant work of three stenographers to answer from 50 to 75 letters a day. He used to tell me he was in constant correspondence with two million women. I used to ask him how he could possibly have anything more to say to them and he would reply that if he lived to be one hundred he would never exhaust the reservoir of information he had stored up. His question-box articles were characteristic and witty and people used to tell me they took the magazine on account of Dr. Wiley's articles and point of view. I recall the lady who wrote and asked him what to do for her wrinkles and he replied characteristically: "Dear Lady. Pull down the shades."

Many Honors Conferred Upon Dr. Wiley

Many honors were conferred upon Dr. Wiley, but the one he most deeply appreciated was when he resigned from the Bureau of Chemistry, and the members of the Bureau, *en masse*, from the smallest to the greatest, presented him with a case of silver, on the cover of which was inscribed:

"To Harvey W. Wiley, whose leadership has been an inspiration to all who have had the privilege of knowing personally, day by day, the breadth and depth of his well-stored mind, his unshakable integrity, and his splendid poise and never failing geniality, under any and all conditions,—from the Bureau of Chemistry, U. S. Dept. of Agriculture, 1883-1912."

Another honor, which he appreciated, was being made a Chevalier of the Legion of Honor of France for his services in 1909 in drafting the French law on the adulteration of wine. This decoration he did not receive until after he resigned from the Bureau of Chemistry in April, 1912, when it was presented to him by the French Ambassador, Jules Jusserand.

Bust of Dr. Wiley by Gutzon Borglum

In 1927 Dr. Wiley's friends asked the late Gutzon Borglum to make a bust of Dr. Wiley. Mr. Borglum's reply was that while he knew of Dr. Wiley and his great work he had never met him; that it

was necessary to get an impression from a man's face and from talking to him. Several days after that interview he met Dr. Wiley at the latter's office in Washington and wired the friends who had asked him to make the bust, "The greatest face since Lincoln's." Shortly before Mr. Borglum's death he stated, "My bust of Dr. Wiley is among the three or four best things I have done."

Dr. Wiley Never Cherished a Grudge

One trait of character which Dr. Wiley possessed which prolonged his life and made him a delightful companion was that he never cherished a grudge and he seldom dwelt on unpleasant happenings. Although his recommendations, based on his scientific investigations and profound convictions, were too frequently reversed notwithstanding his sincere and earnest efforts to support them, Dr. Wiley maintained his equilibrium and cheerfulness. Until his death he retained the keenest interest in the food and drug law. It was his ardent wish that the ideals that he cherished and incorporated in that law should be utilized for the good of the public.

Dr. Wiley Would Approve of New Act of 1938

I am sure he would welcome the new Food, Drug, and Cosmetic law passed in 1938, all the provisions of which, with the exception of one, I have a deep conviction he would approve.

The prevention of false advertising would of course have his hearty approval; also the inclusion of cosmetics within the purview of the law; the promulgation of definitions and standards of identity for foods, with the force of law, was a matter for which he ardently strove; the control of drug products on the basis of therapeutic claims would also be near his heart, and informative labeling would meet with his hearty approval.

Dr. Wiley Would Not Approve the Tolerance for Poisonous Substances

The provision which I do not believe Dr. Wiley would approve would be the tolerance for poisonous substances. He would not, I feel sure, hold a brief for a poisonous substance in food, in any amount no matter how small, and hence he always hailed the Supreme Court deci-

sion in the *Bleached Flour* case where the word "may" was used with great acclaim.

The Court said:

"Flour may be used in many ways—bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food by the strong and the weak, the old and the young, the well and the sick; and it is intended that if any flour, because of any added poisonous or other deleterious ingredient, *may* possibly injure the health of any of these, it shall come within the ban of the Statute."

Dr. Wiley always hoped his views on preservatives and harmful added ingredients would triumph. On June 3, 1925, he addressed an enthusiastic letter to President Coolidge on how he might rejuvenate the food law. Nothing came of the letter.

Dr. Wiley's Grief at the Division of the Bureau of Chemistry

It was a great grief to Dr. Wiley when, without his knowledge until after the appropriation bill for 1927-28 had passed the House of Representatives, the Bureau of Chemistry was divided into the Bureau of Chemistry and Soils and the Food and Drug Administration. It was then he wrote his *History of a Crime Against the Food Law*. The last chapter of that book, written in Dr. Wiley's witty and trenchant manner, expressed his view that the character of the law as he wrote and interpreted it had undergone a change from a punitive measure to a corrective one. If he had survived to this day and had been able to observe the workings of the Food, Drug, and Cosmetic Act during the eight years since its passage, I believe he would have recognized that the modernized version of his law is in keeping with the times; that it retains all of the highly meritorious provisions of his own statute but has been strengthened and clarified and made a more perfect instrument for public protection.

Dr. Dunbar Sees to It That the Consumer Is Fairly Treated

Mr. Walter G. Campbell, a beloved personality and distinguished executive, one of Dr. Wiley's boys, who was the first Food and Drug Commissioner, resigned when he neared the age of retirement. Then Dr. Paul B. Dunbar was appointed. Dr. Dunbar is a Ph. D. from Johns Hopkins and was for a number of years Assistant Chief and Acting Chief of the service. Beginning with a sound educational foundation, he added a technical, practical and sound knowledge of foods and drugs. He has two outstanding traits of character in his work, getting all the

facts, and doing his duty fairly. He sees to it that the consumer is also fairly treated.

Drug Administration Personnel Has Knowledge of Its Job

Probably no branch of the government has a corps of workers which ranks higher in knowledge of the job and in their integrity in carrying it out. All who seek to comply with the law will find the utmost of helpfulness if the question at hand is taken in an open and frank way directly to the member of the force handling it.

General Federation of Women's Clubs Aided Passage of Original Law

Dr. Wiley always gave the members of the General Federation of Women's Clubs a large share of the credit for helping to pass the original law, which he wrote. From 1933 to 1938 we all rallied to the support of the new bill. I became the President of the American Pure Food League, composed of Dr. Wiley's old friends and colleagues, led by Robert MacDowell Allen, former Food Commissioner of Kentucky. In 1906, we were able to muster favorable opinion in successive fights to improve the old law, and for my efforts in this endeavor I was awarded an Honorary Master of Arts Degree from Hanover College, Indiana, Dr. Wiley's Alma Mater.

Dr. Wiley Lived from Days of Spinning Wheel to Days of Airship

Dr. Wiley had the strange experience of living from the days of the spinning wheel to the days of the airship. We were present when President Coolidge pinned a medal on Colonel Lindbergh's coat. This fact is strikingly brought out in the class poem written by Judge Robert Grant, quoted [1] from *Occasional Verses, 1873-1923,* for the fiftieth anniversary of the Harvard Class of 1873:—

". . . what a tale! No genii of the lamp
Could with the touch of magic rival ours,
No mortal ever saw a table spread
With richer fare since man lost Eden's bowers.
Marvel on marvel, change hot-foot with change,
Wizards astride the air and under sea;
Our fifty years of fact have staggered dreams
And dulled the razor edge of fantasy.

[1] With permission of Charles Scribner's Sons.

"To hear the human voice across the world,
To see the winged plane the clouds caress,
Electric light, the auto, the X-ray,
Typewriter, submarine and wireless,
The deadliest war that mortals ever fought,
The slave set free and woman suffrage won
All in one life! Where was the counterpart
In any life of men beneath the sun?"

Dr. Wiley lies in Arlington Cemetery, where lie the great dead of the nation. On his breast is his Grand Army badge and the little cap he wore as a private during his service in the Civil War. On his monument are inscribed the words:

HARVEY WASHINGTON WILEY
1844 to 1930
FATHER OF THE PURE FOOD LAW

and carved in the stone is a copy of the beautiful medallion presented to him on the occasion of his eightieth birthday, by the Association of Official Agricultural Chemists. This medallion depicts the Caduceus of the physician, the stalk of maize of the farmer, an oak branch symbolizing long life and a scroll, depicting the food law, all surrounding the words: "In recognition of his services to chemistry, agriculture, hygiene and the public welfare." [*The End*]

BENZOATE OF SODA AS A PRESERVATIVE

". . . The evidence indicates that the only purpose in adding benzoate of soda is to effect an economy in the cost of the manufacture which amounts to approximately 25% difference in consumer price, resulting in a material economic advantage over competitors who achieve the same preservative quality by the use of a greater quantity of sugar, an approved ingredient. This economic adulteration is the very fraud which the statute [1938 act] was designed to combat." *United States v. 306 Cases, etc., of "Sandford Tomato Catsup with Preservative."*

Original Federal Food and Drugs Act of June 30, 1906 as Amended

.....ITS DISTINGUISHED ADMINISTRATORS

TO BE DISTINGUISHED is to be different; but difference alone does not confer distinction. The three administrators of the Food and Drugs Act of 1906 were distinctly different. Harvey W. Wiley, Carl L. Alsberg, and Walter G. Campbell were alike only in their devotion to a common cause. Each, in his own day and in his own way, rendered unique and significant service to the nation. *That* gives them distinction.

Dr. Wiley Was a Cordial, Courageous Personality

My privilege was to work under the personal direction of each of them. On the first day of July, 1902, exactly four years before the enactment of the food and drug law, I reported to Dr. Wiley at his office in Washington. He was working serenely at a massive desk under a ceiling fan with long, slowly revolving blades. Big of body, clear of head and kind of heart, he was a cordial, courageous personality.

Dr. Wiley's "Poison Squad"

He told me of his plans for a feeding test with twelve young men who would volunteer to serve as guinea pigs. The bill of fare for each meal would include a small dose of a chemical preservative. Controversies in respect to the effects of preservatives on the health of consumers, he told me, had produced much heat but little light. Health

Fred B. Linton . . .
Formerly Assistant to the Commissioner of Foods and Drugs

authorities agreed that formaldehyde was more suitable for injection into the veins of the dead through a syringe than into the blood of the living through milk. But what of sodium benzoate in tomato catsup, or sulphur dioxide in dried fruit?

When a few weeks later the experimental table was in operation, a bright newspaper man branded the boarders "poison squad." The term "poison squad" appealed instantly to the imagination of the press and of the people. Sensational stories about this unique boarding house where, according to reports, poison featured the bill of fare, were widely published. "Doc" Wiley's name became a household word.

Original Act a Monument to Dr. Wiley's Crusading Zeal

Invitations to make addresses poured in from everywhere. He seized the opportunity to crusade with renewed zeal for the food and drug law he had advocated for twenty years. He addressed civic organizations, trade associations, scientific societies, labor unions, church groups and committees of Congress with equal zest and effectiveness. Facts from his feeding tests and his extensive laboratory examinations of the debased foods then on the market, plus the alarming "poison squad" press stories, aroused public sentiment to a pitch potent enough to pressure Congress to legislate. On June 30, 1906, the Food and Drugs Act became the law of the land, a monument to Wiley's crusading zeal.

Dr. Wiley Enforced the New Law with Fervid Zeal

He plunged into the work of enforcing the new law with the fervid zeal that characterized his crusade for its enactment. He organized a staff of inspectors and analysts, mostly young men inspired with enthusiasm for the cause. For the key job of Chief Inspector, he selected a young lawyer who had helped enforce a state pure food law in Kentucky. Walter G. Campbell, the man selected, brought to the work a high degree of inspirational leadership and of intelligent administration.

Wiley interpreted the law to give the greatest possible protection to consumers. When a member of his staff pointed out that a certain action he proposed was not authorized in the law, Wiley exclaimed: "But we must read it into the law!"

Attempt to Drive Dr. Wiley from Federal Service

Bitter controversies followed. Their intensity led to an attempt to drive Wiley in disgrace from the Federal service. After charging him with misuse of public funds through the illegal employment of a specialist, officials of the Department of Agriculture recommended that, in view of his thirty years service, he be permitted to resign. Permitted to resign! To resign under charges! What an ending that would have been for a distinguished career of significant public service!

President Taft, before acting upon the charges and recommendations, sent them to Wiley for comment. To the consternation of Wiley's enemies, the *New York Times* obtained copies of, and published in full, not only the charges but all of the documents on which the charges were based. What a scoop that was! By afternoon, all the evening papers of the nation were screaming in big headlines:

FIRING PURE FOOD CHAMPION—WILEY
REFUSES TO RESIGN

An investigation was made by the House Committee on Expenditures. With characteristic zeal, Wiley took the offensive and charged his opponents with trying to block, at the instigation of commercial interests, the enforcement of the pure food law. His sensational revelations were daily reported in the press throughout the nation.

When the committee hearings were concluded, President Taft completely exonerated Wiley of the baseless charges. Eventually the men who pressed the charges resigned from the Federal service. In March, 1912, Dr. Wiley, having reached the age of 66, resigned in a blaze of commendation from the press and with the applause of a grateful nation.

Dr. Wiley's Decisions Have Stood the Test of Time

The march of time, with its scientific investigations and clarifying court decisions, has settled most of the controversies that centered around Wiley's administration of the law. It is amazing to note how many of his trail blazing decisions have stood the test of time when we consider the speed at which they were rendered, their number and complexity, and the vast commercial and consumer interests involved.

Dr. Carl L. Alsberg Appointed by President Taft

President Taft searched nine months for a man to fill Wiley's shoes. Upon the recommendation of some eminent scientists, he selected Dr. Carl L. Alsberg, then only 35 years old, whose entire adult life had been spent in study in universities here and abroad, and in scientific research in the field of biochemistry. He stepped from the cloistered shelter of a research laboratory to an administrative desk that had been the center of controversies of cyclonic intensity. He had never had so much as a single day's experience in law enforcement work. A less resourceful man than Alsberg would have been overwhelmed by the task confronting him.

Alsberg was attractive in appearance, being so well proportioned that he did not seem as big of body as the weighing machine proved him to be. He spoke several languages fluently. His knowledge of science was extensive. He was a man of vision. His discriminating mind enabled him to concentrate on the essentials of a problem. There was about him an air of reserve power that was impressive.

Dr. Alsberg Felt That Further Advance Must Come from Science

Surveying conditions in the food and drug industries in 1912, Alsberg was convinced that further advance must come from science and

what science could do to improve methods for processing, preserving, storing and shipping perishable foods, and for manufacturing drugs. He believed that many violations of the law were caused by lack of knowledge of technological principles rather than by intent to debase. He inaugurated new research projects. He encouraged food and drug industrialists to establish their own research laboratories to improve their processes and their products.

Dr. Alsberg's Appointment of Walter G. Campbell

At first, Alsberg was handicapped by his lack of administrative experience. In the spirit of a true scientist, he sought the right answer to every question. Until he found it, he would make no answer. Delays in handling inquiries, seizure actions and prosecutions resulted. He learned the hard way that time, which is a minor consideration in research, is of the essence in good administration. He experienced with two assistant chiefs to handle routine administrative problems, but friction between them forced him to conclude that one could act more expeditiously. He then created a single supervisory administrative position and centered in it ample authority for the handling of law enforcement operations below the policy making level.

Nor did he hesitate in selecting the man for the new position. He found him right at hand in the person of Walter G. Campbell, who had won Alsberg's confidence by his intelligence in solving regulatory problems and by his resourcefulness in meeting emergencies. Alsberg, in 1916, gave Campbell wide authority to administer the law.

The Achievements of Dr. Alsberg

Alsberg was then freer to devote his own attention to directing the varied lines of scientific work of the Bureau of Chemistry. Certain academic scientists who were skeptical of research in Federal laboratories and raised their eyebrows when it was mentioned, now found it necessary to watch for the scientific papers from Alsberg's research staff in order to keep abreast of the newer developments in their respective fields. Commercial analysts, who were employed to fight the government in contested court cases, became painfully aware that to challenge the methods, or the accuracy, of the government's analytical work, was to endanger alike their reputations and their clients' cases.

Alsberg's achievements in applying science to agriculture and to the improvement of technological processes, as well as his great contributions to the food and chemical war agencies during World War I, make another story told in the annual reports of the Bureau of Chemistry, and in a biography of Alsberg now in press. He resigned from the Federal service, in 1921, to become a director of the Food Research Institute at Stanford University.

Walter G. Campbell's Administration

Walter G. Campbell was then placed in full charge of the administration of the Food and Drugs Act, and was given ample authority to apply his own plans and policies. Erect and alert, he looked then, as he does today, like the tastily dressed, courteous and highly intelligent professional man he is.

Dr. C. A. Browne, an eminent chemist with an international reputation for his work on sugar, was appointed, in 1923, to direct the diversified scientific work of the Bureau of Chemistry, a task for which he was eminently qualified.

Campbell recommended to the Secretary of Agriculture that a new agency be created solely to enforce food, drug and related laws. With the approval of the President and of Congress, the Secretary, in 1927, established the Food and Drug Administration. Organized and directed by Campbell, that administration operated in the Department of Agriculture until 1940 when, by order of the President, it was transferred to the Federal Security Agency. There it found a warm welcome and a sympathetic environment.

Men and women with varied qualifications, and trained in many sciences, are required to enforce food and drug laws. During Campbell's administration the total number employed by the Food and Drug Administration, including those in Washington and in all branch districts and stations throughout the nation, never exceeded 900 people. The effective enforcement of the law with so small a staff, strikingly reveals Campbell's organizing ability, his inspirational leadership and his wise administration.

Some Federal agencies, set up to do jobs of less magnitude and complexity, have employed twice and even thrice as many people.

Speedy spenders and wanton wasters might well learn from what Campbell did that a small, well organized, well directed group of competent specialists working as a unit towards definite objectives, under a practical plan of operation, can do more and better work than can the agencies which prefer to follow the example of the quick growing mushroom.

Campbell inspired his staff to do more and better work. A resourceful inspector, who declined a tempting offer to leave the Federal service, said to me: "I stick to my job because I like Campbell's leadership." He spoke the sentiment of many others who found their greatest satisfaction in giving the best they had in response to Campbell's quick and generous appreciation of good work.

Even discipline, as administered by him, inspired enthusiasm. A young inspector whose work had slackened in the New York metropolitan area, was called to Washington. As, slumped in dejection, he waited in a room adjoining Campbell's office, he told the receptionist that he had heard by the office grapevine that he was slated for transfer to Savannah. "I won't go," he protested. "I'll resign."

A few minutes later he was ushered into the inner office. The receptionist could only guess what was transpiring during the hour the inspector talked with Campbell, but she smiled when the young man came out briskly, his shoulders thrown back, his head up, his eyes shining with eagerness. He announced triumphantly: "The best opportunity in the United States is in Savannah, Georgia. I go there next Monday. Watch what a good man can do in that territory."

Skill as a negotiator is a must for a Federal bureau head who would operate efficiently. Else he must devote too much time resisting the encroachments of other bureau heads who seek to filch his authority, his functions and his funds. The battles of the bureaus in Washington never cease. Campbell's skill as a negotiator was recognized, respected and feared. An executive who was asked to reconsider a decision, exclaimed: "I won't see Campbell! That man talks me into changing my mind in spite of my convictions."

Industrial leaders who came to convince Campbell of *their* viewpoint, have remained to be brought to *his* viewpoint. Many were glad that he persuaded them to do what proved to be to their own advan-

tage as well as to the best interests of consumers. One industrialist said: "Campbell is too strict, but he is fair."

Congressmen gladly heard Campbell speak for, or against, bills before their committees. They often asked, "What does Campbell say about that?" Not always did they follow his advice, but they repeatedly called for it. You will see why, if you read his clear and convincing arguments on the bills that preceded and led up to the Food, Drug, and Cosmetic Act of 1938. That law manifests Campbell's fairness and wisdom in solving regulatory problems.

Campbell and I retired at the same time in 1944. He turned his work over to a staff which he had selected and trained for the purpose. Under the leadership of Dr. Paul B. Dunbar, that staff will continue to operate under the Campbell policies of wise administration.

Each Administrator Did His Job Splendidly

Each of the Administrators of the act of 1906 was admirably equipped by nature and training to do that particular phase of the work which, at the time he served, was most significant. And each did his job splendidly.

Wiley, the zealous crusader, aroused the nation to the need for the enactment and the enforcement of a pure food and drug law when the indifference of the public and the opposition of certain industries were the obstacles to be overcome. Alsberg, the man of vision, increased the effectiveness of the law and the quality of foods and drugs by his emphasis upon scientific research in both public and private laboratories, when only science could remove the technological difficulties in the way of further advance. Campbell, the inspirational leader, through wise administration which won the confidence of the courts and the cooperation of industries, released all the potential power in the protective provisions of the 1906 law, and obtained in the act of 1938 even more potent power for the protection of the public.

Such were the unique and significant services that confer distinction on Dr. Wiley, Dr. Alsberg and Commissioner Campbell. Now abideth crusading zeal, scientific vision and administrative wisdom, these three; but, for effective law enforcement, the greatest of these is administrative wisdom. *[The End]*

Original Federal Food and Drugs Act of June 30, 1906 as Amended

ITS ADMINISTRATIVE P

Paul B. Dunbar . . . Commissioner of Food and Drugs, Food and Drug Administration, Federal Security Agency

IN ONE OF HIS THOUGHTFUL ESSAYS Walter Lippmann pointed out some years ago that great movements in the way of social reform pass through three stages. There is first the crusading period designed to awaken the public to a recognition of its need and to stimulate it to make its desires known to the legislators in such positive terms that appropriate legislation will be enacted. Next comes the period of adjustment when, with legislative authority established, it becomes necessary to set up machinery and a carefully organized plan to effectuate the legislative intent. Finally comes the long pull when, with the machinery set up, at least in an experimental way, the real task of making the new legislation effective begins. So it was with the Food and Drugs Act of June 30, 1906.

Leaders of Different Stages Have Varying Personalities

Lippmann further observed that personalities of entirely different types usually characterize the leaders in the first stage as contrasted with those of the organizers and administrators who undertake the second and third tasks. This is strikingly true of the outstanding figures who shaped and administered the act of 1906.

Scope of the Subject

My subject deals with administrative progress in the enforcement of that act. In discussing it I shall offer no apology for including personal observations and recollections, since this morning's program designedly includes those who have a background of association with

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the outstanding figures and happenings of the four decades we are now commemorating. I must disclaim any personal knowledge of the legislative or crusading period of many years' duration which preceded June 30, 1906. Others will deal or have dealt with that very vital and interesting period. My own contact with the enforcement picture began on July 29, 1907, when I reported for duty at the old Bureau of Chemistry Building in Washington at what was then Fourteenth and B Streets, Southwest, now Fourteenth and Independence Avenue. The site of that old four-story brick building is now occupied by the northwest corner of the South Buildings of the Department of Agriculture. Incidentally, I was received and sworn into the Federal service by Fred B. Linton, who has preceded me on this morning's program. The official acquaintance begun that morning nearly 39 years ago continued and ripened. His sound judgment as executive officer and business, personnel, and budget manager first of the Bureau of Chemistry and later of the Food and Drug Administration was exercised until the date of his retirement on June 30, 1944. His contributions to the development of a sound governmental organization for the enforcement of this statute cannot be overestimated.

Early Days in the Bureau of Chemistry

But I am ahead of my story. I entered the Bureau of Chemistry as a young and inexperienced chemist just out of Johns Hopkins University.

I was 25 years old and it was my first full-time job. They paid me the munificent salary of $1,000 per annum and it was undoubtedly more than I was worth. My place in the scheme of things was highly unimportant but at least I was impressionable and observant and the impressions gained then and in the ensuing years are pertinent to the development of the subject.

The Bureau of Chemistry as it existed then was small as government units go and small by contrast with the Food and Drug Administration of today. But so was the country. So were the food and drug industries. So was the government itself.

Washington was still a somewhat sleepy, overgrown village. Walking to the laboratory around the south boundary of the White House grounds one could frequently see President Theodore Roosevelt with Mrs. Roosevelt on his arm taking his after-breakfast stroll. It was characteristic of him that regardless of the severity of the weather he was invariably without hat or overcoat. He was a stimulating picture of strength and vitality.

But my own world centered in that little four-story building at Fourteenth and B, Southwest. Closely packed therein were a food laboratory, a drug laboratory, microscopic and bacteriological laboratories, and a number of other units associated more closely with the Bureau's program of agricultural chemical research than with its regulatory duties. In this building, too, were most of the Washington executive offices of the Bureau of Chemistry.

Dr. Wiley Was the Dominating Figure

The dominating figure occupying a spacious office on the first floor was the almost legendary Dr. Harvey W. Wiley. Mark Sullivan, in volume 2 of his absorbing book entitled *Our Times—The United States 1900-1925*,[1] says of him: "* * * easily the outstanding figure in the crusade for pure food was Doctor Harvey Washington Wiley, a very mountain among men, a lion among fighters." Speaking of Wiley's crusade for the passage of the Food and Drugs Act, Sullivan writes:

"Endowed by nature with a capacity for passionate indignation, having the spiritual zeal of a crusader and the physique to endure hard fighting, he dedicated himself to waging war on the evils and to this end launched out on a campaign of public education. * * * Wiley brought to his task of popular education an unusual array of talents. He could write and speak interestingly and authoritatively. He was convincing and per-

[1] Published by Charles Scribner's Sons and quoted with their permission.

suasive. * * * On the platform the forcefulness and originality of his utterances gained from the impressiveness of his appearance: his large head capping the pedestal of broad shoulders and immense chest, his salient nose shaped like the bow of an ice-breaker, and his piercing eyes, compelled attention. He had a keen instinct for the dramatic."

Dr. Wiley Popular with the Press

The entire chapter in Sullivan's book under the caption "The Crusade for Pure Food" will repay reading by the student of this period. It may be added that Dr. Wiley's keen sense of humor and his skill as a raconteur made him extremely popular with the press. He could always be counted upon to give a reporter a good story when news was scarce, and he had no hesitation about uttering fighting words when in his judgment they were called for. That he was popular with the press is evident from the fact that he was the guest of honor at one of the historic Gridiron dinners sometime around 1912. To this day one of the jingles sung on that occasion lingers in my mind. It went something like this:

> When Dr. Wiley comes to town
> The butchers hunt their holes.
> He'll sterilize the pots and pans
> And fumigate the rolls.

To the day of his last appearance before the Association of Official Agricultural Chemists, of which he was one of the founders and moving spirits, his annual talks, which continued I believe to the very last year of his life, were looked forward to by food and drug chemists with keen anticipation. Mrs. Wiley I know will forgive me if I recite one incident at an annual address he gave to the Association a few years after his happy marriage. He announced in all solemnity that he had found the bonds of matrimony extremely easy and comfortable. His explanation was that at the time of his marriage Mrs. Wiley and he had entered into a compact that *he* would make all the decisions on *major* problems and that his wife would make all the minor decisions. Said Dr. Wiley, "I am happy to announce that up to this time no *major* problems have arisen for my decision."

Dr. Wiley Spearheaded the Attack on Adulterated Food and Drugs

Due to his absorption in administrative problems Dr. Wiley knew personally very few of his subordinates in the Bureau of Chemistry. His contacts and his acquaintances in the Bureau were largely restricted to

division chiefs but he possessed the unquestioned loyalty, admiration, and respect of the rank and file of the entire personnel of the bureau even though among the younger members of his staff that loyalty was mixed with awe. He had just come triumphantly through a most grueling legislative campaign of many years' duration. He had spearheaded the attack on adulterated foods and drugs. By the sheer power of his personality, his skill as a speaker, his humor and sense of publicity values he had made himself a household word in the nation and had consolidated behind him national support, both organized and unorganized. Women's organizations rallied to his cause and were joined by professional groups, and even some industrial groups which farsightedly recognized that such a law would spell salvation for the honest enterpriser.

Dr. Wiley Was the Leader, Crusader and Motivating Power in the Legislative Period

Undoubtedly the climax of Dr. Wiley's official career was reached on June 30, 1906, when Theodore Roosevelt affixed his signature to the statute we are today commemorating, and it is just and fitting that his tomb in Arlington Cemetery should bear the inscription "The Father of the Pure Food Law." Dr. Wiley was the leader, the crusader, the motivating power in the legislative period. But the period of organization for the long pull was now at hand. That was the period of my first contact with the Bureau of Chemistry.

Dr. Bigelow Also Shared the Burden in Developing Scientific Evidence

Dr. Wiley was undoubtedly weary after the long grind of the legislative campaign. Looking back from the perspective of nearly forty years I am conscious now that he was deliberately and very properly throwing upon others the burden of organizing a force capable of carrying out the purposes of the law and developing a systematic enforcement plan. During the first few years of my connection with the Bureau of Chemistry I recall that he made a number of extended overseas trips, leaving the management of the Bureau of Chemistry in the capable hands of his Assistant Chief, Dr. Willard D. Bigelow, a man whose name should be honored as one of Dr. Wiley's most loyal lieutenants and one who shared the burden of developing the scientific evidence which established the need for national food and drug legislation.

Food and Drug Inspectors Had Zeal for Public Service

It was fortunate indeed that in the first group of food and drug inspectors who reported for duty in June, 1907, were a number of men who had had regulatory experience in the enforcement of pioneer state laws, who had a zeal for public service, an enthusiasm for the cause of pure foods and drugs, and the ability to direct that enthusiasm towards useful ends. One of these young men was William R. M. Wharton, now Chief of the Eastern District of the Food and Drug Administration, who will follow me on this program. Another was Walter G. Campbell. If Dr. Wiley had made no other contribution to the organization of the Bureau of Chemistry for the enforcement of the law than his instant recognition among the group of able young inspectors who reported to him in June, 1907, of the outstanding worth of Walter G. Campbell, it would have been enough. I am sure there will be no dispute on the part of those who know the part he played, when I state emphatically that no more happy selection could have been made by the distinguished Chief of the Bureau of Chemistry than that of Campbell as Chief Inspector. Campbell's service in that capacity was the beginning of a career in the Federal Government which terminated only when, as Commissioner of Food and Drugs, he voluntarily retired in May, 1944, after 37 years of distinguished achievement. He was in truth the ideal man to take up the work of organization and the long pull of effective enforcement passed on to him by Dr. Wiley, the pioneer and crusader.

Early Difficulties in Proving Food Adulterated

Immediately on reporting for duty on that hot July day in 1907 I was assigned to the food laboratory of which L. M. Tolman was Chief and was placed under the direction of one of the more experienced chemists. I was given a small bulletin containing official methods of analysis and assigned a number of samples of vanilla extract for examination. I was puzzled as to why such comparatively unimportant products were selected for early attention. The reason soon became clear. There was a considerable degree of debasement in food flavors. Attention to this field, therefore, was undoubtedly justified at some stage, but the reason they were then selected was because they were easily obtained by inexperienced inspectors and particularly because in the limited number of official methods there were satisfactory and reliable assay procedures for these flavors.

It soon became evident that the efforts of the inspectors alone would be largely abortive unless laboratory techniques for all types of products could be developed in such a way as to keep pace with current regulatory needs. Innumerable samples were submitted by inspectors whose observation at the point of manufacture had convinced them that the products were adulterated and sometimes entirely unfit for human consumption. Evidence based on objective laboratory examination of these samples, however, was essential if the cases were to be successfully presented in the courts; and laboratory procedures were completely lacking in too many instances, or, if methods had been proposed, they produced erratic and unreliable results.

Effective food and drug law enforcement could not be obtained by dispatching inspectors to various sections of the country with instructions to collect, and submit to the nearest Bureau of Chemistry laboratory, specimens which they believed to be adulterated or misbranded. It was easy to find such specimens. It was self-evident, however, that if the analyst was to keep abreast of the inspector's needs more reliable methods of analysis must be developed with the direct objective of proving to the satisfaction of any court that the suspected adulteration did exist.

Development of New Analytical Methods

While this realization was dawning upon us there had begun a series of unfortunate controversies between Dr. Wiley and other governmental officials which occupied much of his time and energy during this period. This is not the place to discuss them. Unquestionably they embittered the last days of Dr. Wiley's service in the Bureau of Chemistry. He retained to the end of his life a conviction of the fundamental soundness of his ideas. Few there are today who will challenge them. Notwithstanding these controversies definite progress was being made in the way of organizing an effective enforcement program. Inspectors were being trained. Laboratories under qualified chemists had been opened at strategic points throughout the United States, building on a nucleus of a few port laboratories established in 1903. The chemical staffs of these units were alert to their opportunities and showed initiative in the development of better analytical methods. Inspectors using these laboratories as their bases travelled throughout the contiguous territory investigating the manufacture of foods and drugs, collecting samples

from interstate shipments, and reporting their findings to the laboratories with suggestions that still further analytical methods be developed. The Washington Laboratories in particular concentrated on the development of new analytical methods. It was at this time, for example, that outstanding studies were begun by Burton J. Howard, head of the Microchemical Division, for the purpose of developing microscopic methods to demonstrate the presence of decomposition in vegetable products. Many will agree that the researches of Howard with his microscope were a major influence in bringing the American food industry to the point of public acceptance which it has reached today.

Combination of Penalties and Educational Approach

Promptly there developed the concept that the most effective way to enforce a statute like the Food and Drugs Act was to combine the penalties afforded through seizure and criminal prosecution with an educational approach designed to demonstrate to well intentioned manufacturers how to produce legal products. Dr. Wiley initiated such a program early in the period following the passage of the law. It was continued under Dr. Wiley's successors. Today it is an accepted fact that effective enforcement inposes obligations on the enforcing agency to aid manufacturers in all reasonable ways to conform with the law.

Defects in Original Statute

It was not long before the law was required to meet the acid test of court trial and interpretation. It has been well said that the Food and Drugs Act of 1906 was one of the most beneficent pieces of legislation ever passed by Congress. Dr. Wiley and his co-workers had framed a measure which was remarkable in its scope for that period of our history. In the main, the cases instituted by the Bureau of Chemistry were successfully pressed through the courts, but as time went on defects appeared in the statute, some anticipated, some unexpected.

Lack of Authority to Establish Legal Standards for Food

The lack of authority to establish legal standards for foods was early recognized as a handicap to enforcement. Dr. Wiley, in cooperation with state officials, had labored diligently to formulate a comprehensive series of food standards. They were useful in that they gave

reputable manufacturers an administrative guide. To the extent that they were accepted by industry—and they were largely accepted—they had the effect of stabilizing manufacturing procedure, but at best they were administrative opinions only. The courts invariably required proof of their common acceptance in any contested action.

Difficulty in Proving That False Claims Were Fraudulently Made

An even more serious problem arose in the application of the drug section of the law to misbranded proprietary medicines. The Supreme Court in 1911, in a divided opinion in the case of the *United States v. Johnson*, held that the language of the law defining misbranding did not apply to misrepresentations as to curative effects. Steps were immediately taken to remedy this defect. The Sherley Amendment, enacted August 23, 1912, was the result. It declared as misbranding the use of false and fraudulent statements concerning the effect of drugs in the treatment of disease. This amendment fell far short of accomplishing the desired results. It imposed upon the enforcing agency not only the task of proving the worthlessness of a medicine but also of establishing that false claims were fraudulently made. Cases directed against dangerous nostrums were lost because it was impossible to prove that the responsible shipper knew the claims were false. These reverses demonstrated that extensive, costly, and time-consuming investigations must be made to prove that false claims were fraudulently made. The difficulties and costs of preparing well-grounded court actions against nostrums were thus measurably increased. Eventually, nearly twenty years after the passage of the Sherley Amendment, a selected group of inspectors was given special training in methods of collecting evidence of fraud. When such evidence was developed through painstaking investigations the success of the court proceedings was almost a foregone conclusion.

Appointment of Dr. Carl L. Alsberg

Dr. Wiley resigned in 1912. His official career had extended over a period of 29 years. There followed a brief interval when the Bureau of Chemistry was directed by R. E. Doolittle, an able food chemist who had served as Chief of the New York port laboratory and who subsequently served as Chief of the Eastern Food and Drug Inspection District and later the Central District. Mr. Doolittle continued as Acting Chief

of the Bureau until the appointment on December 16, 1912, of Dr. Carl L. Alsberg as Chief.

Contributions of Dr. Alsberg

Dr. Alsberg was a man of entirely different temperament from Dr. Wiley. He had no regulatory experience, but possessed the keenly developed mind of a researcher and a sincerity and simplicity that earned the respect of those who came in contact with him. Alsberg's contributions to the program of agricultural research of the Bureau of Chemistry were outstanding. This was his major interest. He was conscientious enough, however, to realize that he had a serious obligation to carry on effectively the regulatory duties of the Bureau. His most important contribution to the regulatory picture was the organization in 1914 of the present district system. Its purpose was to effect a certain amount of decentralization of the control of enforcement work by establishing three food and drug inspection districts under the direction of competent field officers or district chiefs. The plan did away with the centralized direction of the inspector group from Washington and placed the management of the inspectors as well as the chemists in the various field stations under the district chiefs and immediate laboratory chiefs. The Chief Inspector, Mr. W. G. Campbell, was designated as Chief of the Eastern Food and Drug Inspection District, and L. M. Tolman and B. R. Hart were appointed to head, respectively, the Central and Western Districts. The district chiefs began at once to organize their districts which, in boundary and general make-up, were essentially the same as they are today.

The Project Plan

There developed promptly the concept that food and drug enforcement operations, to be made most effective, must be organized on a project basis. The project plan in simple terms means that offenses are classified in the order of their importance from the standpoint of public health and economic interest with a concentration of regulatory activities against the most serious and so far as possible in a uniform manner throughout the United States. To effectuate this plan the inspection force must acquire full knowledge of prevailing practices in every branch of the food and drug industries to insure prompt detection and correction of violations through appropriate legal action. Food and drug enforcement work is never static. Conditions change. Ad-

ministrative attitudes are of necessity altered as additional scientific facts become available or as court interpretations extend or narrow the scope of the law. Industry attitude and the progress of industry both necessitate changes in the approach. Always in the operation of the project plan the concept is kept in mind that the law is designed for the protection of the consumer and the consumer's interest must receive first consideration.

Dr. Alsberg's Annual Report of June 30, 1917

The period of Alsberg's service as Chief of the Bureau of Chemistry embraced the strenuous days of the first world war. His annual report for the year ending June 30, 1917, reviews the first ten years of the enforcement of the Food and Drugs Act and recites the fact that more than 6,000 cases were terminated in the courts during the first decade of enforcement. He calls attention to the need for strengthening and clarifying amendments. He comments on the fact that one of the consequences of the enactment of the Food and Drugs Act was to stimulate the enactment of similar legislation in many of the states. He points out the difficulties confronting manufacturers where state and Federal requirements are dissimilar. He records the reestablishment of the Joint Committee on Definitions and Standards, consisting of representatives of state enforcement agencies and the Federal Government, and the setting up of an Office of State Cooperation to promote uniformity between state and Federal enforcement operations.

Resignation of Dr. Alsberg

Dr. Alsberg resigned on July 15, 1921. His influence on the research program of the Bureau of Chemistry was profound, but he made real contributions to a more effective enforcement organization. During the ensuing period and until his successor was appointed, the Bureau was directed by W. G. Campbell as Acting Chief. He had served under Alsberg as Assistant Chief in charge of regulatory work but had steadfastly refused to accept the chiefship of the Bureau on Alsberg's resignation, in the belief that a scientist should head the organization.

Dr. Browne Becomes Head of Bureau of Chemistry

Dr. Charles A. Browne became head of the Bureau on July 1, 1924. Dr. Browne is a distinguished chemist. He headed the sugar laboratory

under Dr. Wiley and has made many valuable contributions in the field of agricultural chemistry. As was to be expected of a trusted lieutenant of Wiley, he assumed his duties with an enthusiasm for enforcement as well as a keen interest in the scientific researches on agricultural problems then being carried on by the Bureau of Chemistry.

Food and Drug Administration Formed

Upon assumption of the chiefship by Dr. Browne, Mr. Campbell became Director of Regulatory Work of the Department of Agriculture. In this capacity he continued to maintain a directing interest in the work of food-law enforcement. In the 21 years since the enactment of the Food and Drugs Act of 1906 the regulatory duties of the Bureau of Chemistry had become increasingly burdensome and had inevitably interfered with the program of agricultural chemical research which the Bureau of Chemistry was originally organized to promote. The decision was accordingly reached to separate the law-enforcement activities of the Bureau of Chemistry from that bureau and to assign them to a separate organization. Thus on July 1, 1927, the entire law-enforcement organization of the Bureau of Chemistry was incorporated in a new bureau first known as the Food, Drug, and Insecticide Administration and later as the Food and Drug Administration. Its direction was entrusted to Walter G. Campbell and continued under his guidance until the date of his retirement in May, 1944.

Food and Drug Administration Gave Impetus to Enforcement Activities

The establishment of the Food and Drug Administration as a separate bureau gave an impetus to the enforcement activities, demonstrating the wisdom of the decision to establish it. The plan of enforcement already described was changed in no material respect. Soon after its formation, however, the Administration began a campaign for amendment or revision of the act of 1906.

Passage of Federal Food, Drug, and Cosmetic Act of 1938

Campbell's annual report for the year ending June 30, 1931, notes that the year completed 25 years of food and drug law enforcement and that in the quarter-century 18,000 regulatory actions had been instituted. He devoted a section of the report to recommendations for strengthening

amendments. The demand for an expanded and more modernized law received new impetus during the fiscal year 1933, with the interest of the President of the United States and the sympathy and cooperation of the Secretary and Assistant Secretary of Agriculture. A bill to supplant the act of 1906 was drafted in the Department of Agriculture, approved by the Department of Justice, and introduced in the Senate on June 12 of that year by Senator Royal S. Copeland of New York. A fixed premise observed in the drafting of this proposed new measure was that all of the many worthy features of the act of 1906 should be preserved. This is not the time nor place to review the legislative history of the ensuing five years which resulted in the passage and approval, eight years ago this very day, on June 25, 1938, of the Food, Drug, and Cosmetic Act.

Effects of Food and Drugs Act of 1906

And so the Food and Drugs Act of June 30, 1906, approached an honorable end. It continued in partial effect until all the provisions of the new statute became operative. It had accomplished incalculable benefits in the way of protecting both the American consumer and the honest manufacturer of foods and drugs in the 33 years of its existence. Its useful life had spanned a whole generation. It was the instrument which had raised the standards of American foods and drugs probably to the highest of any nation, and had effected vast improvements, not to say revolutions, in the manufacture of these commodities. The concept that the interests of the honest manufacturer and consumer are identical has been firmly established as a result of its operations.

Transfer of Food and Drug Administration to Federal Security Agency

The present pattern of enforcement rests on the sound foundation laid throughout the 33 years of enforcement of the parent statute. Such changes as have occurred since 1938 are merely the logical extension made necessary by the added provisions of the new measure. On June 30, 1940, the Food and Drug Administration was transferred from the Department of Agriculture to the Federal Security Agency. The title of Chief of the Food and Drug Administration was changed to Commissioner of Food and Drugs. The transfer was a logical one and involved no change in procedure or plan of operations. The sympathy and interest which has been accorded the work of food and drug law

enforcement in the new environment is manifested by the presence here on this program as an active participant in these proceedings of the Honorable Watson B. Miller, Administrator of the Federal Security Agency. In all sincerity I can assert that the Federal Security Agency has demonstrated the same interest in the welfare of the consumer and of the honest producer that Dr. Wiley envisioned when he began his long battle for the enactment of the Food and Drugs Act of 1906, more than a half-century ago.

[*The End*]

APPRAISAL OF PROGRESS

"During the short life of the new law we have in our enforcement operations encountered in abundance disappointments and discouragements. That, however, may be expected with any public service work of this character and scope. Construction of an enduring administrative course is not a succession of unretarded advances. Diversions and circumvention of serious obstacles give rise to impatience. Appraised at such periods, the progress to date has not been what it should be. On such occasions it becomes opportune briefly to review the history of food and drug control. When we do, we realize that the advent of a Federal law for that purpose is within the memory of all of us. Then when we compare the general conditions of that day with its prevalent adulterating and misbranding practices with the condition of three years ago when control under the old law had reached the optimum point, we conclude that the country has cause for self-congratulations." Walter G. Campbell at a meeting of Association of Food and Drug Officials, October 22, 1940.

Original Federal Food and Drugs Act of June 30, 1906 as Amended

ITS INSPECTION

WE ARE MET TODAY to celebrate the anniversary of one of the great milestones of contemporary history. We are now within a few brief days of the fortieth year since President Theodore Roosevelt approved an Act of Congress designed to protect the health and welfare of the American people. When June 30 next shall have crowded all the intervening days from the calendar and shall have itself passed into oblivion with the rest, 40 years will have intervened since the nation for the first time exercised its authority over commerce to protect its entire food and drug supply from adulteration and misbranding, by the passage of the Food and Drugs Act of June 30, 1906.

Passage of Law a Monument to Dr. Wiley

The passage of this law was an achievement which will stand throughout history as a monument to the courage, vision, wisdom and humanitarianism of the father of the law—Doctor Harvey W. Wiley. His accomplishment was realized after years of labor and bitter disappointments, and in spite of the mean, sordid, and selfish opposition of commercial interests whose operations faced restriction by the law's terms.

Historical Periods in Development of Regulatory Processes

My place on this program is to record very briefly the development of regulatory processes used in the enforcement of the act. I shall consider the subject from the standpoint of four historical periods. The first or preliminary period from the earliest times down to 1885 was the period during which food regulation was concerned in its earliest

NEVOLUTION

W. R. M. Wharton
Chief, Eastern District, U. S.
Food and Drug Administration

stages with decomposed foods only and later with the detection of simple adulterations of a very limited number of individual foods by physical testing. This period also marked the elementary beginnings of the use of analytical chemistry to detect adulterations. The second period between 1885 and 1906 saw the extension of the application of simple tests to a wider variety of staple foods; expansion of knowledge of prevalent forms of adulteration; extension of knowledge of normal compositions of foods; progress in the drafting of purity standards for foods; and continuing development of scientific analytical methods of adulteration determination. The third period covering the first seven or eight years of the life of the Food and Drugs Act of 1906 witnessed the employment of all the means of control which had been developed up to that time, a trend toward control of industries rather than primarily of products (the latter known as the objective procedure); a continuation of the development of standards, analytical methods, and procedures. This led to the fourth, or current period, wherein systematic and planned operations replaced objective procedures which experience had shown to furnish isolated, sporadic and haphazard results. The objective sample collection and examination method was replaced by the project plan of operation. This plan contemplated operation at the source of violation, seasonal timing, selective activity—industry-wide coverage and mass action for corrective purposes where necessary.

Early Writings on Food Adulteration

One of the early writers on the subject of food adulteration was Frederick Accum, whose revelations of food adulteration practices in England appeared in 1820. Accum and later authors, including Frederick A. Filby, discuss the duties of food inspectors about the year 1100 A. D. who were called "Pepperers," because they tested pepper, and of later food control agents called "Garbelers." Their duties included "the custody of weights, the responsibility of detecting efforts to defraud the public by mixing old things with new, or things of one class with things of another, moistening merchandise such as saffron, alum, ginger and cloves to increase weight." Their tools were "sieves with such holes that not only the dust but also the gravel must go through." They also separated products light in weight from the good by air currents.

An Early Food Inspection Operation

One of the early food inspection operations in the United States, according to tradition, occurred in California about the year 1834. Shellfish-growing areas of the coast of California were a principal source of food of the Mendocino Indians, natives of that State. Experience had shown that consumption of shellfish at certain times of the year produced what was known as paralytic shellfish poisoning. Poisonings occurred coincidentally with the appearance of so-called red water in the areas where the shellfish grew. It is a well-known fact now that shellfish feeding upon certain forms of red plankton acquire therefrom a very poisonous alkaloid known as Gonyaulax. This is true today on the west coast and the Canadian and Maine east coast. At times plankton is present to such large extent as to give the water a reddish tinge. The association of the deleterious effect with the occurrence of red water caused the Chief of the tribe to appoint a watchman to warn off and keep away any seekers of shellfish at the time when the water was red. One day the old Indian Chief himself, having need to replenish his larder, strolled down to the waterfront. Here he encountered his inspector and was warned away with the admonition "red water!" The old Chief had a look himself and at that particular moment saw no red water, so he pushed the inspector aside and walked in and got himself a mess of clams with fatal results. This was the first exercise of political

interference with food control in America.—Would that it had been the last!

Caveat Emptor in the Mercantile Age

By the middle of the 19th century, economic adulterations had become widespread, constituted of short weights, dilutions and substitutions. Chemical preservatives made their appearance in foods. "Beer was adulterated in taverns, wine by vintners by mixing spoiled with good." "Milk became a medium through which much water was sold at a profit." With the development of the mercantile age, the doctrine of *caveat emptor* gained a firm foothold after its exploitation by traders as a protective measure.

The English "Sale of Food and Drugs Act" of 1875

The English "Sale of Food and Drugs Act" of 1875 was enforced largely to reach prevalent economic types of violations. The processes of detection included physical and limited chemical testing performed on samples of staple foods as sold at the retail level, with penalties assessed against the sellers.

Enforcement of Early State Food and Drug Laws

In the decade before the opening of the present century, food laws of limited scope were under enforcement in a dozen of the states of the United States. Review of some of the annual reports of these state operations indicate almost universal application of enforcement procedures based upon collection of samples at the retail level and legal action against the retail seller. These reports refer to the presence of formaldehyde and boric acid in milk, the watering and coloring of skimmed milk, the adulteration of maple sirup with cane sugar, and fictitious names and addresses of manufacturers.

Additional state laws coming into effect between 1900 and 1906, and some of the older ones prohibited the manufacture and sale of adulterated and misbranded products, but available records show very few actions against manufacturers. For the most part, in that period regulatory attention was given to milk, vanilla extract, lemon extract, molasses, canned goods for short weight, maple sugar, vinegar, wine, cider, beer, whiskey, coffee, rye and buckwheat flour, stock feeds and honey.

Early Food Standards

Regulatory processes evolved from the simpler to the more complex fields as new methods of detection of adulteration were made available, as purity standards were established, and as the industrial age developed. Some of the early definitions of foods set up as standards are of interest because of their limited scope. For example, Pennsylvania about 1901 declared fruit juices to be "the juice or pulp or both of fresh, sound fruit of the variety specified on the label without the addition of any other substance," and vanilla extract to be "the solution prepared by the masceration of vanilla beans with alcohol and sugar."

Dr. Wiley's Scientific Work in Behalf of Food Standards

The necessity for providing a yardstick or standard on which to judge food products and methods for applying the standard was early recognized by Dr. Wiley. From the very beginning in 1883 when he became The Chemist of the Department of Agriculture, he pursued researches directed toward determining normal compositions, adulterants, nutritional values and standards for a variety of foods. These researches are reported in a series of scientific bulletins. Best known of these is No. 13, issued in 10 parts, between 1887 and 1902. These discoveries were not only an important factor in securing public support for the passage of the Food and Drugs Act of 1906, but also became useful in the enforcement of that act.

Association of Official Agricultural Chemists' A. O. A. C. Book

The Association of Official Agricultural Chemists was formed in 1884. It began immediately a study of chemical methods of examination of foods and drugs and from modest beginnings brought out new and improved methods year by year until today the current A. O. A. C. Book of Methods furnishes the finest and best tested analytical methods in the entire world. Dr. Wiley was a sponsor and influential member of this Association.

National Association of Food and Drug Officials Established

In 1897, the National Association of Food and Drug Officials was established, meeting for the first time in Detroit, Michigan. Dr. Wiley

was one of the organizers. Its object was to secure uniform, unified and cooperative action. It held its fiftieth anniversary in Atlanta, Georgia, during the present month.

Products in Official Compendia Now Standardized

The Food and Drugs Act of 1906 established the descriptions in United States Pharmacopœia and National Formulary as official standards for drugs named therein. The 1938 act added the descriptions in the United States Homœopathic Pharmacopœia as the official standards for products named in it.

The products named and described in these *compendia* are therefore officially standardized as to identity, strength, quality, and purity and they must meet the descriptions and standards so set forth.

Appropriation Acts of 1902 and 1903

The Appropriation Bill of the Department of Agriculture of June 3, 1902, appropriated funds

"to enable the Secretary of Agriculture, in collaboration with the Association of Official Agricultural Chemists and such other experts as he may deem necessary, to establish standards of purity for food products and to determine what are regarded as adulterations therein, for the guidance of the officials of the various States and courts of justice."

The Agricultural Appropriation Act approved March 3, 1903, contained a similar provision and in addition authorized the exclusion from import of "imported foods found dangerous to health because of adulteration and those falsely labeled with respect to place of manufacture or contents of package." Dr. Wiley established the second field laboratory in New York for this purpose on September 6, 1904. One had been established shortly before at San Francisco. Somewhat later, port laboratories were established at Boston, Philadelphia, Chicago and New Orleans for the same purpose.

Carrying out the provisions in the Appropriation Acts of 1902 and 1903, authorizing the establishment of food standards, Office of the Secretary Circular No. 10 was issued November 20, 1903. Circular No. 17 was issued March 8, 1906. Circular No. 19 was issued June 26, 1906. Circular No. 136 was issued May 14, 1919. Service and Regulatory Announcement F. D. No. 2, dated September 19, 1927,

followed and underwent five revisions, the last of which was published November 5, 1936. Review of these publications shows continuous progress in standardizing foods.

Early Enforcement of 1906 Act

It is not strange that after the Food and Drugs Act became law on June 30, 1906, the initial enforcement work should follow much the same pattern as had been used in England and our own states. Objective procedures were employed. These involved the indiscriminate collection of samples and the chemical examination thereof. Violative foods and drugs were thus sorted from legal products. Legal actions against shippers were often based upon single and isolated violations. Many of the early legal actions were on minor violations. Emphasis was given to economic cheats.

In their early operations, Federal inspectors were furnished with a list of products, samples of which were to be taken from stocks that had been shipped in interstate commerce. This list included cider, molasses, gluten flour, coffee, vanilla extract, honey, vinegar, spices, wine and whiskey. A limited field, according to present-day practice.

Review of the first 100 Notices of Judgment representing court cases terminated under the 1906 law, shows that 60 referred to seizures and 40 represented prosecutions. Divided another way, 89 represented economic violations, 3 involved violations of health significance, and 8 covered medicines, those principally bearing false therapeutic brandings. Examining the 89 economic violations, we find 25 involved shortages of weight alone. Ten were based upon misbrandings as to name and address of the manufacturer and geographic source. The fines in the 40 prosecution cases in this group averaged $67.00. A considerable number were $5.00 or under.

Of the first 100 court cases referred to, only Notices of Judgment Nos. 50 and 68 recite a background other than that

"The Inspector collected a sample and this was found on examination to be in violation."

Notice of Judgment No. 50, covering lead-chromate-coated coffee, recites

"An Inspector obtained evidence that the coffee was adulterated by addition of a coating of lead chromate and subsequently (after seizure) examination of samples confirmed the evidence theretofore obtained by the Inspector."

Notice of Judgment No. 68 covering so-called bourbon whiskey, recites:

"Investigation by an Inspector * * * at the distillery in New Orleans disclosed that for several years prior thereto the distillery had produced no spirits made from grain mash but only from a product of molasses and water."

Modestly, I may say that I was the investigating inspector in both of these instances.

The first year of operation under the 1906 act was a busy one. It ended June 30, 1908. By that time the six port laboratories previously established were enlarged and re-equipped, and 11 new branch laboratories were established in the field. The staff laboratories in Washington were extended and enlarged—a drug division was organized. Work was planned to develop new analytical methods to cope with other forms of adulteration, and to extend knowledge of normal product composition. During this period the development of inspection techniques lagged.

In its annual report at the end of the 1908 fiscal year, the Bureau of Chemistry said

"the work for the inspection force the following year will include continuation of operations for the suppression of interstate sale of distilled malt and wine vinegars as apple and cider vinegar; time will be given to the adulteration and misbranding of spurious liquors and whiskies; milk investigations will be undertaken at cities so located as to receive interstate supplies of milk; investigation of sophisticated waters purporting to be those of natural mineral springs will be rigorously pursued; effort to suppress the branding of inferior coffees as Mocha and Java and the sale of domestic cheese as imported products will be increased; stock feed manufacturers which adulterate wheat products with rice hulls, corn cob meal and other adulterants will be given coverage. Finally, systematic campaign will be directed against breaking up the practice of over marking canned goods and staple food products as to quantity of contents."

This was a limited program.

Now we may stop briefly to take stock of the situation which existed at the end of that first year of the enforcement of the act of 1906. The passage of this act had sounded the death knell to the doctrine of *caveat emptor;* the doctrine "public interest comes first" was now fairly well on its way to become generally recognized. A considerable amount of information was at hand concerning the prevailing adulterations and misbrandings of the common foods and drugs. An organization had been formed and staffed with chemical and inspectional forces. A limited number of the more common foods had been standardized on an advisory

basis—their normal compositions had been determined. Methods and means of their chemical analysis had been provided. The enforcement activities had begun to cope with the situation as it then existed, under a law later to be shown to be faulty and ineffective in several respects and to be successively amended, and finally to be superseded in 1938 by a powerfully revised statute designed to cope with multiple abuses and conditions inimical to public welfare which had accompanied the vast expansion of trade and commerce. The 1938 law extended control to cosmetics and medical devices. It required elaborate informative labeling. It greatly increased penalties for violations. It provided for injunction to restrain violators. It authorized the making of legal standards for foods. W. G. Campbell brought all of this about.

Changes Occurring from 1906 to 1946

In the period since 1906, there has been greater industrial expansion than had theretofore occurred in all history. These industrial and social expansions gradually influenced the directions in which control methods and techniques were developed. 1906 was the age of protein-fat-carbohydrate food value estimation; today is the vitamin and amino-acid age. That may be called the patent medicine age; this, the vitamin, chemico-therapy, anti-biotics age. This is the package age, the delicatessen age—that was the age of home production and bulk distribution.

Meantime our population has increased from 85,000,000 to 140,000,000. The value of annual commerce in the articles under control has increased from a few hundred millions to 25 billions. Products under supervision have grown from about 100,000 to considerably more than a million items. Firms and individuals amenable to the terms of the Federal Food, Drug, and Cosmetic law now number more than 100,000.

From the comparatively small beginning of the early part of the century, the growth to these dimensions has been gradual with accelerated speed in the last decade. For example, it has been reported authoritatively that since 1940 the cosmetic industry has increased 250 millions of dollars in output business value.

Historically, it is worthy to record the change in attitude on the part of industry during the period 1906-1946. Food, drug and cosmetic producers quite generally recognize now that food, drug, and cosmetic law enforcement in the public interest genuinely reacts to industry's

advantage. Modern industry too believes that food and drug law compliance is its best policy. Industry trade associations' activities have contributed largely to this new thinking.

Factory Inspection Introduced by Walter G. Campbell

Among the 29 inspectors who reported to Dr. Wiley in Washington on May 31, 1907, was Walter G. Campbell. He had come to the organization with food law enforcement experience in Kentucky. He was made chief inspector immediately on reporting for duty.

Chief Inspector Campbell early recognized that the process of seeking out violations of the act by collecting extensive numbers of samples indiscriminately was a wasteful process because it required the sampling and chemical examination of hundreds of items to detect a limited number of violations. He reasoned that if a product was found at fault in one location and isolated action was taken in such circumstances, this would leave on sale to the public adulterated products of the same kind in many other places. He found by experience that because of the large number of dealers and product multiplicity, adequate coverage was impossible with the forces available. Experience had shown also that the objective procedure resulted in discrimination and faulty public protection because the law was applied to one manufacturer and not to others practicing the same form of violation. Moreover, the method used was not fundamentally corrective because the penalties assessed for a single violation were so small that they failed to be deterrent.

By the end of the first decade of the present century, Chief Inspector Campbell had influenced a change of procedure. The new system, devised better to achieve consumer protection, was predicated upon the proposition that the detection of violation should be as nearly at the source of the violations as possible; that is, at the factory, mill, processing plant or the producing area of the articles. He said if the inspection force could be trained to recognize violations during the course of product manufacture, then all of the acts of violation of the violator could be determined at one time in one operation. Mr. Campbell then instituted an intensive training course in factory inspection technique. This was a great turning point in control procedure.

While the old law did not furnish definite authority to make factory inspections, they were rarely refused by the factory owners. Trained

inspectors visited plants, studied raw materials and factory processes, and determined likelihood of violations. Here the sorting of legal from illegal products was done at the source and follow-up for the collection of samples to be examined for confirmatory purposes was performed only in cases where reason to suppose violation existed. Products dangerous to health were speedily and completely removed from the market by seizure action, since the factory inspection system furnished a means of acquiring knowledge of distribution and location of all such violative products either of a single manufacturer, or an entire industry.

Project System Put into Effect by Campbell in 1914

In 1914, a project system of operation was put into effect under Mr. Campbell's stimulus. This system was anchored in the fact that the public interest demands that things of first importance should be given first attention; i. e., violations of the law having adverse effect on health should receive first regulatory attention—illustrations: foods containing poisonous ingredients, potent drugs dangerous to health when taken as directed. Hygienic violations which affect the aesthetic sensibilities should be considered of next importance. Illustration: products which are filthy, decomposed, or putrid. (Some of these are also dangerous to health.) Third in the scale of importance: economic violations; i. e., those contributing major frauds. Technical and minor misbrandings of little public significance were to be ignored or corrected by correspondence.

The next development came as a result of continuing appreciation of the fact that commercial expansion had brought many new abuses which adversely affected the public welfare. If the administration of the law with the limited means available was to be even acceptably effective, there must be applied the most highly systematized scheme of control possible in the circumstances. Accordingly, in 1914, to meet these conditions and to increase efficiency, the Bureau of Chemistry underwent reorganization. Direction of the field service was decentralized. Three Districts were formed with a single official in charge of each. District territories were subdivided into Station territories. Here, too, a single individual directed the activities of both the inspection and scientific forces. The laboratories and the inspection forces had formerly been directed separately from Washington. The reorganization furnished an opportunity to launch on a formal basis a systematized plan of operation.

This was done. It had developed under Mr. Campbell's stimulus and it became known as the project plan of operation, as already stated. A bureau project schedule was set up under various general classifications covering the entire field of foods and drugs. The main classifications were broken down into product classifications and under each were recorded all the known forms of violations and these were characterized as of first, second, third, or inconsequential importance. Starting with the master project plan as a base, each Station was required to prepare a work plan for a year in advance subject to monthly revision. The Stations set this plan up to meet the needs of the territory under control, giving due consideration not only to the importance of violation, but also to output-volume and dietary significance. All producers in each category were listed in order of planned attention.

Total man hours available for the entire year were estimated and percentage allotments of this time were assigned to the various projects depending upon their relative importance in the territory under consideration. In making these time percentage allotments, reserves were set up for exploratory operations; to study industries and their practices; to perform surveillance to detect new forms of violation; to follow up on detected illegal practices, and for court attendance. The plan included means of coordinating District and Station operations.

System Further Perfected under 1938 Act

The system has been further perfected since the 1938 act was passed. Since then also, inspectors have been specifically trained for the duties not embraced in the old law; for example, for making sanitary factory inspections and for making detailed inspections of control systems used in drug and food plants.

The planned project system of operation, the integration of the inspection operations with those of the laboratories, the development of highly trained specialists in the technique of inspection of the most intricate and complicated processes of manufacture of foods and drugs, had been accomplished when the Food, Drug, and Cosmetic Act of 1938 became effective. The enforcement of this new act was launched with a minimum of confusion, with an absence of false starts and lost motion, and with a degree of selectivity which produced immediate results in extremely important fields of control of foods, drugs, cosmetics and devices. The 1938 law provided authority for federal inspectors to

make factory inspections, an element of authority required for effective operation of the developed inspection system.

By way of contrast with the first one hundred Notices of Court Judgment under the old law, I refer now to one hundred recently published Notices of Judgment under the new law. Forty of these deal with adulterated and misbranded drugs, practically all having health danger significance. (D. D. N. J. 1351 to 1390.) The fines average $2,000, with a maximum fine of $18,000. In one case, the operator of the violating drug manufacturing plant served three months in jail for a serious drug violation.

In the 50 court judgments representing foods (F. N. J. 7926 to 7969, 8001, 8025-6-7, 8033-4), 29 were criminal prosecutions, based on serious adulterations including danger to health, filthy products, filthy factories and serious economic cheats. Twenty represent seizures for similarly serious reasons. The maximum penalty was $5,000 and six months suspended jail sentence, based on the use of a poisonous ingredient in beer. One case involved an injunction restraining a creamery from shipping filthy butter in interstate commerce.

In the case of ten cosmetic Notices of Judgment (C. N. J. 96 to 105), four represent products dangerous to health because of dangerous ingredients, three additional represent products containing an artificial color capable of producing cancer in experimental animals. One was based on filth in a cosmetic product and two charged seriously false claims.

Inspectors Are Highly Trained Scientific Investigators

Finally, Mr. Chairman:—Federal Food and Drug Inspectors were originally sample collectors. Today they are highly trained scientific investigators. The early Federal inspector's equipment consisted of one expandable net shopping bag to carry samples. These were early discarded because of feminine implication. Today inspectors are equipped with scores of devices of complicated nature to aid in arriving at the truth concerning the identity and purity of foods and drugs and for determining insanitary conditions in plants. For example, ultra violet lamps to detect certain indices of filth are standard equipment. Food and drug inspection has rightfully taken its place side by side with analytical procedures in food and drug control work. It well and faithfully serves the public welfare. It has come into its own as a science. This has been its evolution. *[The End]*

The National Food, Drug and Cosmetic Law Instituted by the 1906 Act

A FUNDAMENTAL LAW OF THE LAND

J. Howard McGrath

AS STATED by the late Franklin D. Roosevelt,

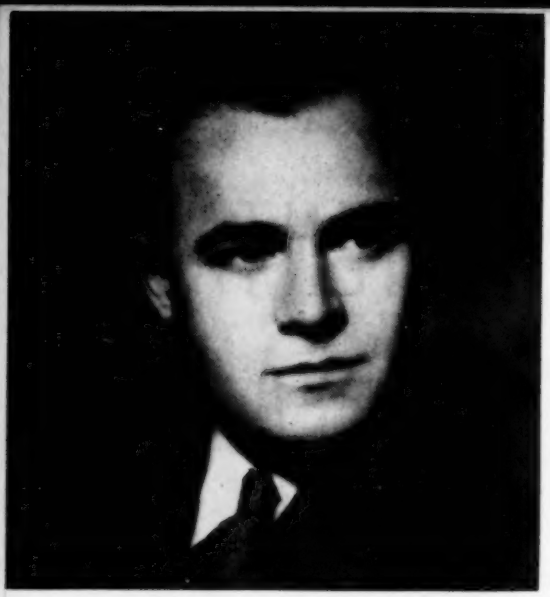
"The great majority of those engaged in the trade in food and drugs do not need regulation. They observe the spirit as well as the letter of existing law."

Unfortunately, however, there have always been a few who have put personal greed above the well-being of their customers, and who have not hesitated to enrich themselves and cheat their neighbors by debasing their merchandise.

Regulation of Adulteration in Ancient Times

The attempts of organized society to prevent the adulteration of food and drugs date back to ancient times. The racket implicit in the purveying of adulterated and misbranded commodities is not a new one by any means—it has been practiced from the commencement of recorded time. "There is death in the pot," was cried to Elisha to warn him that the herbs of which the pottage was made were poison weeds. Pliny the Elder, prior to the destruction of Pompeii by the Volcano Vesuvius, complained that "white earth" was added to the bread baked in his day.

Of great importance in antiquity were pepper, and beer and ale; pepper because it was used extensively as a preservative for meat, and beer and ale because people then, like people now, enjoyed drinking them. Attempts to regulate the sale of these products were not infrequent. Both Athens and Rome took steps to prevent the adulteration of wine. In 1316, the pepperers or spicers of London began to regulate the quality of their produce. During the reign of William the Conqueror, brewers were subject to severe fines for adulterating beer and were ridden about the town so that they might receive the well-earned abuse



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of their fellow-citizens. Food control statutes were passed in France and Germany in the thirteenth century. The first pharmacopœia was published in England by the College of Physicians in 1613. In fact, some of these laws may have out-distanced ours, for in the fourteenth century the Prevost of Paris forbade the artificial coloring of butter. In the United States, Congress enacted a law to prevent the importation of adulterated and spurious drugs and medicines as far back as 1848.

The Food and Drug Industry Is a Product of the Growth of Cities

Patterns of thought and behavior, as well as social and economic conditions, do not remain static or quiescent. What sufficed in biblical times was inadequate in the days of the knight, or thereafter in the days of the crossbow. The establishment of the industry in food and drugs is largely a product of the growth of the city. In the dawn of human existance people were too busily engaged in merely existing to develop industries and industrial processes. With the growth of cities, however, the scattered gatherings of people, formed primarily for self-protection, ceased to be self-supporting. It became necessary to obtain food from other sources, and the maintenance and safeguarding of an adequate food supply became a problem of government.

The fall of the Roman Empire, and the dissolution of its attendant civilization, caused many existing economic channels to disappear, and a diminishing of the importance and place in society of the city. The bases of the economic system of the Middle Ages were the fair and the

itinerant peddler, and the greater portion of the internal commerce of Europe was carried on at fairs, which thus became the chief medium of commercial traffic in distant products. There was always a great demand for spices, presumably one of the causes of the crusades, but there was no widespread distribution of foodstuffs and consequently no great urgency for the imposition of regulatory controls. As the Dark Ages grew to a close, however, there was a constant drift to, and growth of, towns. With the further development of towns, it was the artisan's shop rather than the home which became the primary source of manufactured goods. As bread baking, the production of wine and beer and other industries became recognized trades, the government, and various monopolistic guilds which were soon established, began, of necessity, to regulate them.

Industrial Revolution Stimulated Growth of Food and Drugs Industry

It was the industrial revolution which enabled a limited number of manufacturing establishments to create commodities for the entire population, and a fairly small portion of the population engaged in agriculture to produce sufficient food to satisfy not only themselves but the cities. An inevitable accompaniment of this process was a stimulation in the growth of the industries in food and drugs. This development can be stated to have been retarded in this country. As indicated, Europeans tended from the Middle Ages on to gather themselves together in groups, primarily to defend themselves against marauders. The settlers who came to this country, however, were required to be practically self-sufficient in order to cope with the exigencies of pioneer life. It was an unusual household indeed which did not raise enough food and make enough clothing to be practically self-sufficient. The ending of the Indian Wars, however, the settlement and civilization of the entire area of this country, the tremendous growth of the population, and the rapid growth in our transportation and communication systems and industrial processes, soon changed this.

The development of tremendous industries which distribute their products throughout the four corners of this nation, and the resultant intricate problems of distribution, caused new and serious questions to arise in the safeguarding of the health and welfare of the people, particularly with respect to the regulation of the industry in food and drugs.

In such a civilization, the ordinary consumer was in no position whatever to judge the quality or fitness of the wares he was purchasing. Thus, the Supreme Court of the United States pointed out only recently that food and drug legislation is designed to reach phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.

Inevitable Conditions Encountered in Enactment of Regulatory Legislation

There are always certain inevitable conditions encountered in the enactment of regulatory legislation. There is the influence of that group which has a real concern for the public welfare, but which possesses, in addition, interests which cause it to seek precautions against abuses in the administrative process. There is the "Yes-But" element which, when any regulation is attempted, commences by declaring that it is for effective legislation and then attempts to emasculate it by a multitude of weakening amendments. For example, an officer of one corporation, in testifying before a Congressional Committee at the hearings on one of the bills which culminated in the passage of the 1938 act, stated that his organization had "reached the definite conclusion that the proposed legislation in its general purposes as well as in perhaps most of its specific provisions, should be adopted as a measure for the better protection of the public health," and promptly submitted more than forty amendments. Lastly, of course, there is the small, selfish element that is opposed to any regulation at all. These countering cross-pulls are always present when remedial social legislation, such as that involved in the control of the sale of food and drugs, is proposed.

Conditions in the United States in the Nineteenth Century

The conditions prevalent in this country in the nineteenth century were distinctly unsavory. Complaints against the conditions then prevalent could have been made in the tone employed by an English pamphleteer in 1592. This Elizabethan muckraker declared, in a *Quip for an Upstart Courtier:*

"And for you goodman baker, you that love to be seen in the open market-place upon the pillory, the world cries out on your wiliness: You crave but one deere years to make your daughter a gentlewoman. You buy your corne at the best hand,

and yet will not be content to make your breadweight by many ounces. You put in yeaste and salt to make it heavie: and yet all your policie cannot make it. The poore crie out, the riche find fault, and the lord maior and the sheriffs, like honorable and worshipful maiestrates, every daie walk abroad and weigh your bread, and yet all will not serve to make you honest men."

The laws which were passed in the United States usually had the self-interest of industry at heart, for reform was imperative in many instances to safeguard sales, particularly to the export trade. For example, the condition of our cattle and meat products was such that, during the latter part of the nineteenth century, European countries commenced restricting the importation of cattle from the United States. By 1888, eleven countries had prohibited the importation of pork products produced in this country.

Struggle for Food and Drugs Act of 1906

But as far as the domestic trade in food and drugs was concerned, there was vigorous opposition to the imposition of regulatory controls. Subsequent to the introduction in Congress in 1879 of the first general bill establishing safeguards in the interstate sale of food and drugs, a bitter struggle ensued for over twenty-five years. It was the publication of Upton Sinclair's *The Jungle*, which incidentally but glaringly exposed the horrible conditions of the stockyards, and the "embalmed beef" revelations of the Spanish-American War, which led to the enactment of the Meat Inspection Act. And Samuel Hopkins Adams' and Norman Hapgood's revealing articles on patent medicines in 1905 and 1906, and similar outcries by Edward Bok, Mark Sullivan, and others, did much to further the constant struggles for Federal legislation. It is difficult, forty years thereafter, to grasp the magnitude of the task of the proponents of the Food and Drugs Act of 1906 and the bitterness of the opposition to it. Eleven bills were introduced in the first session of the Fifty-Ninth Congress. An important portion of the press, and an aroused public opinion, were behind the fight for effective legislation. President Theodore Roosevelt had declared that he was in sympathy with such legislation, and in his annual message to Congress he stated:

"I recommend that a law be enacted to regulate interstate commerce in misbranded and adulterated foods, drinks, and drugs. Such law would protect legitimate manufacture and commerce, and would tend to secure the health and welfare of the consuming public. Traffic in foodstuffs which have been debased or adulterated so as to injure health or to deceive purchasers should be forbidden."

Senator McCumber, in advocating the passage of the bill introduced by Senator Heyburn, pointed out that

"at this age no man can possibly prepare his own food and his own drugs. He is therefore at the mercy of his fellow-men. His life is threatened at every point by the greed and avarice of the manufacturers of drugs and many kinds of food products."

The opposition, however, was neither weak nor passive. Many of the arguments subsequently levied at, and tactics used in attempting to render innocuous, the 1938 act, more than thirty years thereafter, were employed. Opposing bills were introduced, tactics of delay were engaged in, and the cry was raised that vast, arbitrary, and unconstitutional powers would be given to the bureaucrats. But the bill was eventually passed, and marked an important milestone in mankind's constant efforts to protect itself from the greedy and unscrupulous.

Bases of Broad Outlook of Non-Marginal Producers and Distributors of Food and Drugs

It is important to realize the bases for the present reasonable attitude and broad outlook of the non-marginal producers and distributors of food and drugs towards regulatory legislation—their willingness, in fact their alacrity, to accept regulatory control. The first is that possessed by any decent citizen—the realization that the consuming public is entitled to protection against the charlatan and cheat. The second is the knowledge that every intelligent businessman has—that not only is it to his definite advantage to get rid of that unfair competition which is based on economic cheat and fraud, but that a public confidence in the soundness and honesty of his wares will, as a logical proposition, stimulate their sale. As stated by the then Secretary of Agriculture, when one of the bills which resulted in the enactment of the Federal Food, Drug, and Cosmetic Act was introduced,

"I think it is generally understood that this bill is intended primarily to protect consumers. At the same time, it should operate in the interest of all honest manufacturers."

It was presumably these reasons which, after the passage of the Food and Drugs Act of 1906, caused the enactment of three amendments. It was the sponsorship of the interested industries which caused Congress to define and standardize "butter" for the purposes of the act, to authorize the Secretary of Agriculture to establish a standard of quality, condition, and fill of container for each class of canned foods, and to

permit the Secretary, upon the application of any packer of sea food, to designate inspectors to examine and inspect such food and its production, packing, and labeling.

1906 Regulations Did Not Suffice to Cope with Changes in Later Decades

What was adequate in the type of society which existed in this country in 1776 was not sufficient in 1906. And that type of regulation which met the chief problems present in 1906 did not suffice to cope with the changing problems of the subsequent decades. In addition to the fact that there were serious omissions in the Food and Drugs Act of 1906, even when passed, economic and social changes were rapid. The truck began to weaken the importance of state boundaries. It was not only the strumpet or courtesan who added to her beauty, or concealed her plainness, by paints and rouges. It became important to be informed, not merely not to be misinformed. The span of life increased, with a commensurate growth in the so-called diseases of modern civilization. The vitamin discoveries were made. People began to read newspapers and periodicals more widely, and the discoveries which were to give us *"Portia Faces Life"* and other soap operas were thrust upon a credulous world. Thus, as early as 1917 the *Report of the Chemist* pointed out:

> "While the accomplishments of the Food and Drugs Act have been considerable, it must be admitted that it has its serious limitations. Especially conspicuous ones are the lack of legal standards for foods, of authority to inspect warehouses, and of any restriction whatever upon the use of many of the most virulent poisons in drugs; the limitations placed upon the term 'drugs' by definition which render it difficult to control injurious cosmetics, fraudulent mechanical devices used for therapeutic purposes, as well as fraudulent remedies for obesity and leanness; the limitation of dangerous adulterants to those that are added so that the interstate shipment of a food that naturally contains a virulent poison is unrestricted. Furthermore, the law fails to take cognizance of fraudulent statements covering foods or drugs which are not in or upon the food or drug package."

Passage of Federal Food, Drug, and Cosmetic Law of 1938

The weaknesses of the Food and Drugs Act of 1906 were accentuated by the many changes not only in our economic conditions but in our behavior and manner of thinking. The glib legal phrase *Caveat Emptor* was not so readily accepted at its face value by large segments of the population. The horrendous thought was asserted by some that, under certain circumstances, perhaps the motto *Caveat Venditor* should apply—that possibly it was the seller who should be cautious and

circumspect in vending his wares to the many John Does who made up this nation and were in no position to protect themselves. This important variation in our economic philosophy, together with the vast changes in our mode of living, were largely instrumental in the enactment, after five years' deliberation and controversy, of the Federal Food, Drug, and Cosmetic Act of 1938. While the statute has its imperfections, a brief resume of its major accomplishments (aided tremendously by the liberal manner in which our courts have construed it) reveals that the statute was a tremendous step forward and in consonance with the spirit and needs of the times. Thus, the act brought within its purview cosmetics, mechanical devices offered for curative purposes, and devices and preparations claimed to bring about changes in the structure of the body; more informative labeling was required; a drug was declared to be misbranded unless its labeling bore adequate directions for use or if it was dangerous to health under the conditions of use prescribed in its labeling; the promulgation of definitions and standards of identity for food was prescribed; the addition of unnecessary poisonous or deleterious substances, and the establishment of tolerances when the substances were required in production, were provided for; the operation of factories under Federal permit was prescribed, under certain circumstances, in order to protect the public health; inspection provisions were added; more stringent penalties for violators were prescribed; and false advertising of foods, drugs, and cosmetics was prohibited by the Wheeler-Lea Amendments to the Federal Trade Commission Act.

Opinion of the Trades of the Statute and Its Administering Agency

No social piece of legislation can be effectively enforced unless it is supported, and viewed with sympathy, by those it affects directly. The act represented, as many statutes exhibit in our democratic system, a series of compromises, a process of give-and-take. As enacted, it was not all that its proponents, and more than its opponents, desired. But that by-and-large it is a beneficial piece of legislation, and that it represents a progressive stride, no reasonable man can dispute. The opinion of the trades regarding the statute and its administering agency was well set forth in a recent editorial in the *Drug Trade News*. Said the editorial writer in part:

"The forthcoming observance of the 40th anniversary of the Food, Drug and Cosmetic Act and its forbearer, should be a suitable tribute not only to the basic philosophy and objectives of the act, but also to the cooperation given by the food, drug and cosmetic industries in making it so outstandingly successful.

"Profound indeed have been the achievements of this act. While the law lays a burdensome hand upon the food, drug and cosmetic industries, nevertheless, the passing years have seen a progressively steady deepening of their devotion to the act and of their confidence in the Food and Drug Administration, the enforcement agency.

"The constructive administration of the law as carried on by the F. D. A. is proof that business does not resent regulation per se. Intelligent discipline of industry, based upon an honest adherence to the known purposes and aims of the law, rather than seeking their perversion, has a valid place in the American scene."

Fundamental Philosophy of Food and Drug Legislation

This talk was introduced by a brief quotation from a message sent to the Congress by the late Franklin Delano Roosevelt in connection with the passage of the Federal Food, Drug, and Cosmetic Act of 1938. I can conclude in no better fashion than by quoting more fully from that message, which expresses most eloquently the fundamental philosophy of food and drug regulation. The late President declared:

"Every enterprise in the United States should be able to adhere to the simple principle of honesty without fear of penalty on that account. Honesty ought to be the best policy, not only for one individual or one enterprise but for every individual and every enterprise in the nation. * * *

"No honest enterpriser need fear that because of the passage of such a measure he will be unfairly treated. He would be asked to do no more than he now holds himself out to do. It would merely make certain that those who are less scrupulous than I know most of our producers to be cannot force their more honest competitors into dishonorable ways.

"The great majority of those engaged in the trade in food and drugs do not need regulation. They observe the spirit as well as the letter of existing law. Present legislation ought to be directed primarily toward a small minority of evaders and chiselers. At the same time even-handed regulation will not only outlaw the bad practices of the few but will also protect the many from unscrupulous competition. * * *"

[The End]

The National Food, Drug and Cosmetic Law Instituted by the 1906 Act

Its Basic Significance for Public Health

I AM GLAD of the opportunity to speak to you this afternoon, because in my opinion this meeting symbolizes an important trend of our times. Forty years ago, when the Pure Food and Drug Bill was before the 59th Congress, many of the industries which some of you represent, were opposed to the proposed legislation. In 1938, however, the same industries backed the greatly strengthened Federal laws governing the content, labeling and standardization of food, drugs and cosmetics. And finally, today, a professional association, representing the same industries regulated by the Pure Food and Drug Law, meets to celebrate the anniversary of that law.

Joint Responsibility of Industry and Public Health Service

We, in the Public Health Service, like you of the food and drug industry, long have recognized the determined influence of Dr. Harvey Wiley in shaping the basic legislation. He consistently supported the principle that safeguarding the purity and strength of foods, drugs and biologics is a proper and important function of government on behalf of the people. The record shows that the Marine Hospital Service, predecessor to the Public Health Service, and at that time the only Federal health agency, actively urged the enactment of the original food and drug law. In addition, the Public Health Service since 1902 has been directly responsible for the licensing of biologic products. In this work it has developed a relationship which, over a period of years, represents one of the outstanding examples of co-operation and mutual understanding between industry and government.

All of these mileposts in the legislative history of drugs and biologics control mark very real contributions to the public health. Through

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Harris & Ewing Photo

them untold sickness and death have been prevented that otherwise would have occurred. Our success to date has generated a public confidence that is as sobering as it is gratifying. You in industry and we in government are looked upon as guardians of the public health, and we have the joint responsibility for maintaining and strengthening the safeguards already established, and for developing new ones as needed.

The signs along our road point out quite clearly the value of industry-wide adoption of self-imposed standards in advance of restrictive legislation. They indicate also, as you can testify through your own industry balance sheets, that a philosophy of business practice based upon the welfare and protection of the consumer contains a major element of success.

People's Demand for Public Health and Medical Care Programs

The original food and drug law was an important landmark in health legislation. The fortieth anniversary of the law comes at a time when we can count great gains along these lines. Today there are no less than 170 measures before the Congress concerned directly or indirectly with health. They deal with medical care, mental health, medical research, dental research and service, a nation-wide network of hos-

pitals and health centers, the training of health personnel, the prevention of stream pollution, and many other important problems. They are tangible evidence of the people's demand for public health and medical care programs strong enough to make greater inroads against sickness in our land, and make them more quickly than we have in the past.

We cannot afford to be complacent about our food and drug standards, nor in a larger sense, about our public health achievements as a whole. We are faced with the challenge of keeping pace with the swift moving frontiers of science and with the expanding social concepts of man's responsibility to promote the well being of his fellow man. New drugs and biologicals are constantly being developed whose manufacture and distribution may require additional safeguards. Penicillin and streptomycin are but two of the most recent examples.

Concern Over Advertising Techniques Promoting the Sale of Products

In our efforts to protect the public in the manufacture and sale of food and drugs, we cannot help feeling a deep concern over some of the advertising techniques promoting the sale of products to the general population. In this field standards self-imposed by the industries are urgently needed. I am referring particularly to the widespread use of extravagant claims and promises held out or implied in drug advertising on the radio. At almost any hour of the day, listeners may hear announcements offering relief for a wide variety of human ills. In many of these cases no factual information is supplied to limit the hopes that may be aroused by the appeals. Although the physician is referred to at times in glowing terms, there is too seldom any reference to the importance of seeking competent medical diagnosis or treatment. An announcement which recommends that a certain product be taken every morning and night by everyone over 35, or states that three out of four persons suffer from vitamin deficiencies which are correctible by taking X brand of vitamins, obviously is not in accord with the therapeutic needs of the population. These are only samples of a trend that in my opinion is reaching disturbing proportions.

In the American pattern any product which is to be sold widely must be advertised. Radio is an important medium. Often, however, the enthusiasm of the sponsor gets out of bounds.

Radio Can Take Example from Newspapers

In setting improved standards for drug advertising, radio can look to an excellent example. Some years ago the newspaper industry took aggressive action in cleaning up drug advertising in their columns. A few representative and socially conscious newspapers of the country led the way and most of the others since have followed. Today many papers go so far as to conduct surveys to be sure that advertised products conform to established standards.

It is not too much to hope—even to expect—that the radio industry will do the same or even a better job once the need for such action has been made clear. Radio's contribution to public service has been notable. It has contributed to the advancement of health knowledge among the masses of our people.

The establishment of safeguards in drug advertising offers another opportunity for public service. You who are so keenly interested in both the welfare of the drug industry and the rights of the common man might appropriately work out this matter with the leaders of radio and advertising.

International Health Meeting

The upsurge of action to protect the individual's health and promote his welfare is moving not only toward higher national goals, but toward world-wide goals calling for international planning and action in the field of health. Even now, there is convened here in New York an assembly of historic significance in the annals of public health and in which you have a very large stake. I am referring to the international health meeting which opened on Wednesday of last week. This is the first general conference called under the auspices of the United Nations. It is the largest international health conference ever held, and the most representative. Health is an appropriate subject for the first general conference, since if full cooperation among the nations is not forthcoming in this field there can be little hope for such cooperation in more controversial fields. Inevitably, there will be some differences, but I am confident they will be resolved. The leading public health experts of the world are gathered here, and these first few days have been marked by a scientific and professional atmosphere.

The speed with which this meeting has been called following the signing of the Charter of the United Nations in San Francisco a year ago, testifies to the thoroughness of preliminary foundations. It testifies also to the practical value of previous international experiences in health agreements, even as limited as they were. In 1851 the French government called an international conference to discuss uniform quarantine codes. Soon after the turn of the century there came into existence the *Office International d'Hygiene Publique* and the Pan American Sanitary Bureau, which at the outset were concerned primarily with administering treaties and dealing with the exchange of epidemic intelligence and preventing, through quarantine, the spread of disease from one country to another. Later these two organizations expanded their programs into other important fields. The League of Nations established a Health Organization which was highly successful. At one time or another, important studies were sponsored in malaria, nutrition, rural hygiene, syphilis and leprosy. International exchange of students and health experts was fostered. And, as you all know, significant progress was made in the standardization of drugs and biologicals. This is sound heritage of experience upon which the new international health organization will draw. The tasks ahead are great, but their accomplishment will bring great rewards.

Our government last year expressed its willingness to join the other major powers in sponsoring an international health conference and offered to act as the host for it. However, since the United Nations was being shaped so rapidly, it was agreed that the conference might more appropriately be held under its aegis.

Preparatory to the New York meeting, there was convened in Paris in March of this year, a technical committee commissioned by the Economic and Social Council of the United Nations to draft a preliminary charter for the proposed world health organization. It is this document which the health conference at Hunter College is now discussing.

Proposed Charter of International Health Organization

The Committee of experts which met in Paris proposed an organization sufficiently flexible and with enough authority to deal comprehensively with all international health problems, both those of an emergency nature and those endemic problems which are always with us.

A basic concept of the proposed charter, or constitution, is that health is a state of physical fitness and of mental and social well being, not only the absence of infirmity and disease; that the right to health is one of the fundamental rights of every human being, without distinction of race, religion, political belief, economic or social condition. This philosophy meshes at many points with that of the United Nations, which is dedicated to improved standards of living for all peoples, to a fuller life, a richer life. The fundamental freedoms can be realized and maintained only when people are healthy, well nourished and protected against disease.

The interdependence of nations in the field of health is widely recognized. The realization that lines on maps do not prevent the spread of disease is underscored time and again. The experience of any nation in the promotion of better health is of value to all other nations and, conversely, substandard health services and failure to control epidemics in any nation constitute a common danger.

Specifically, if the substance of the preliminary charter is adopted, the world health organization would, among other things:

Assist governments in strengthening their national health services, including loan of technical experts when requested to do so.

Assist in the development of an informed public opinion among all peoples on matters of health.

Promote more effective methods for the prevention of disease, the improvement of health and the extension of longevity through more intensive scientific research on an international scale.

Foster professional education through improved standards of teaching and training in health, medical and related fields by means of fellowships, courses, study tours and exchanges of visits.

Evaluate medical care plans and services from the point of view of both medical and hospital practice.

Promote, with the co-operation of other specialized agencies, the improvement of nutrition, working conditions, housing, and related environmental factors affecting health.

Standardize diagnostic procedures as desirable, and develop, establish and promote international standards for pharmaceutical, biological and related products.

World Health Organization Would Be World Health Center

In short, what we expect from the world health organization when it comes into operation is a dynamic world health center. Here, the most up-to-date knowledge of the world would be assembled on every

subject pertaining to health, medicine and the related sciences. Here the nations of the world would go for information and for help.

We have come a long way since the early days when international health action was limited to quarantine against cholera, plague and smallpox. We are now on the threshold of a health concept that is universal in scope of action as well as in geography. You can readily see, therefore, that the health problems to be encountered—in fact those already being encountered—cut widely across the relations between nations. Many other international agencies touch the field of health. For example, the Food and Agriculture Organization is concerned, on a worldwide basis, with nutrition; the International Labor Office with industrial hygiene and social insurance; the Civil Aviation Agency with the spread of disease through rapid transport; the Trusteeship Council with the health of dependent peoples; the Narcotics Commission with habit-forming drugs. It is to be expected that the world health agency will work with these and other agencies in technical matters and join with them in reaching a common goal. It is contemplated, also, that the Economic and Social Council of the United Nations will act as the coordinator to prevent overlapping, and gaps, in those fields with which two or more specialized agencies are concerned.

In the same way as official agencies are being brought into the over-all plans, so it is expected that leaders like yourselves will be asked to give the benefit of your interest and wise counsel when plans of international action are being formulated. The pending proposal which would strengthen and expand international standards for pharmaceutical, biological and related products should be gratifying to you. As experts, you can provide guidance and support for a constructive world-wide program to raise and maintain standards for foods, drugs and medical devices.

Standards Should Apply to Products for Export or Import Trade

In approaching this objective, we are of course fully aware of the splendid work that has been carried on in the development of drug standards by the various nations through voluntary and public agencies. Here in the United States the official *compendia* recognized under our laws are the work of experts chosen by the respective medical and pharmaceutical organizations. The standards for drugs and biological

products in these *compendia* are of the highest order. It is but natural, therefore, for us to feel that these standards should apply to products supplied for export or import trade, as well as to interstate commerce. As you know, there are some countries which have no standards at all for the manufacture, distribution and sale of drugs.

As a further objective, I hope we can agree that products failing to meet standards of the nation in which they are produced should not be dumped into international commerce. Such a policy would not only protect the public's health but also would promote sound international commerce and friendship.

Based on this premise, it is obviously desirable that minimum international standards be devised for drugs and biological products in common use.

Need for International Teamwork in Respect to Food and Drugs

In the matter of foods, a similar task awaits the appropriate international bodies. The nutritional aspects of the program might well be a joint undertaking for the Food and Agriculture Organization, and the world health organization.

It is clear, therefore, that there is a need for further international teamwork in respect to food and drugs. Although a beginning has been made on the establishment of international standards, the job yet to be done is one of magnitude. The value of uniformity in the various national pharmacopœia has been recognized for many years. The necessity for the unification of standards for drugs in universal use and for uniformity in strengths and formulae of preparations of drugs has been well recognized but requires further implementation.

Uniform System of Nomenclature Needed

A uniform system of nomenclature is likewise a basic consideration. It is particularly important that in all countries the same name shall designate a drug of the same standard of strength and composition. Furthermore, it is important that the labels of drugs set forth clearly the standard under which the drug is sold. Differences in national standards and nomenclature are a drawback to the spread of medical and pharmaceutical knowledge. They cause serious difficulty for physicians

and constitute a possible danger to patients. Let me give you an example of what I mean. Sulfonamide is known by that name only in the United States. This identical drug is sold under more than twenty names in another country.

Need of a Compilation of Food and Drug Laws of the Different Countries

Another pressing international need in the field of our common interest is to compile and publish the food and drug laws of the different countries. At the present time these laws are not available in a central place nor in a single language. If they were compiled and published, together with other basic health laws and administrative health patterns of the various countries, an invaluable reference source would be established. This type of clearing house is one important element in establishing international biological and pharmaceutical standards.

Compiling the food and drug laws of all nations, and establishing uniform drug standards are but two of the initial steps that might be taken in a comprehensive program for the international standardization of food and drugs. Such a program is, in turn, but a part of the larger world health movement.

Tribute to Representatives of Industry

In the historic effort upon which we are now embarked I ask your encouragement and your support. While my topic this afternoon was the contribution which our food and drug laws have made to the health of our people, I could not overlook this timely opportunity to pay deserved tribute to you who represent the industry. Neither could I resist asking that we turn our eyes to the living future where so much depends upon our actions now.

An international opportunity impends. It is an international obligation as well—an obligation which falls heavily upon each person in this room. We have as our goal in the world health organization the same sort of teamwork between governments and industries that we have developed so effectively. We who are helping lay the foundations of world health look for the same guidance and help from the drug industry on an international scale as we have had in meeting national problems.

[*The End*]

The National Food, Drug and Cosmetic Law Instituted by the 1906 Act

ITS BASIC VALUE to FOOD INDUSTRY

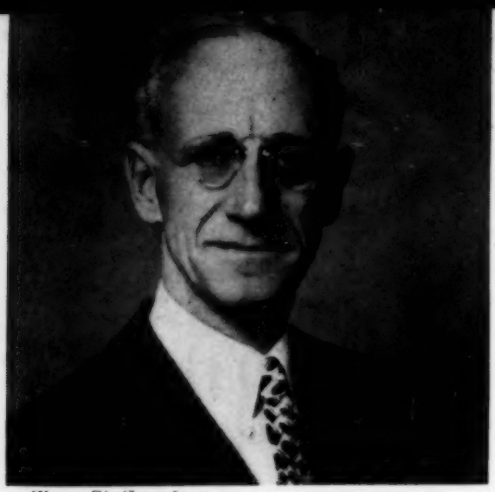
Clarence Francis

TO SOME there may be a seeming paradox in the fact that a businessman welcomes, as I do, this opportunity to praise a regulatory law. There is, I assure you, no paradox at all. For I believe that, whenever a regulatory measure is soundly conceived and justly administered in the public interest, it will be warmly supported by industry. I am happy, therefore, to bespeak the true gratitude which American food manufacturers feel for the Federal Food and Drug Act and its great sponsor, Dr. Harvey W. Wiley.

Business Was in Accord with the Objectives of the 1906 Act

Anyone who studies the records of the Congressional hearings which preceded the passage of the 1906 act must be impressed by two things. First is the fact that the crusading spirit of Dr. Wiley was tempered by a scientific respect for facts and by an attitude of rational compromise. Second, the degree of business participation in this legislation was, I think, remarkable at the time. The Congressional committeemen gave business witnesses an attentive and reasonable hearing —and this included even those few who were not too reasonable themselves.

The record shows further that the majority of businessmen, with certain unhappy exceptions, were earnestly in accord with the objectives of the proposed law. This was a significant symptom of a dawning change in business philosophy. The spirit of *laissez faire* was still



Chase-Stutler photo

Mr. Francis is
Chairman of the Board,
of the
General Foods Corporation

strong, to be sure, but *caveat emptor* as a rule of conduct was no longer considered adequate to protect the consumer.

Ethical distinctions were frequently blurred, however, and one man's chicanery was often another man's "Yankee ingenuity." For example, it seems, from the record, that a great deal of "pure Vermont maple syrup" originated in Iowa and that the abundance of this product appeared to increase with the distance from its supposed source. This represented a sort of business practice which no one would defend today, of course, but I think it should be better understood that its perpetrators were a minority even then and that they were roundly condemned by their more scrupulous competitors.

Similarly, it should be pointed out, in justice to the responsible food processors of the time, that the differentiation between adulteration of food by deleterious means and adulteration by the use of unacknowledged but harmless substitutes was not clearly understood by the public. Adulterations of the first kind were widely dramatized and emphasized. As usual, the guilt of a few brought suspicion upon many.

Dr. Wiley himself observed, during the 1906 hearings, that if he were to enter an average grocery store and select 100 items at random, he would probably find that—coffees and spices excepted—about five of the items were adulterated. Within the guilty minority who made those five items, it was still another minority who wittingly or wilfully sold dangerous or injurious foods. And I should suppose that the number of these would correspond to the percentage of the criminal element which one is likely to encounter in any human group or any stratum of society.

Most Manufacturers Wanted to Operate Honestly

Nevertheless, the honest manufacturer had a hard row to hoe prior to the passage of the act. In examining the testimony, one comes again and again upon the statement that most manufacturers wanted sincerely to operate honestly and urgently sought some means of curbing the unscrupulous competitors whose practices were discrediting the entire industry. It was, as I say, a period of change. A new slogan, "Honesty is the Best Policy," was being widely propounded and accepted in an atmosphere of growing moral maturity, so to speak. Dr. Wiley found something to take hold of, therefore, when he addressed his persuasions to the better elements in business.

Sane, Progressive Businessmen Always Favored a Rational Regulatory Law

Yet again we will not pretend that there was no greedy minority. One existed and it unleashed a savage lobby against Dr. Wiley and the principles for which he stood. But it *was* a minority—and meanwhile the majority was beginning to pull together. National trade associations were few at the time. Through those that existed, however, the impulse of business toward self-regulation was beginning to find expression. A case in point was the fledgling National Confectioners' Association which was waging its own war on the malefactors of its own industry. It asked only that Congress enact a law in conformance with others whose passage it had already secured in a number of states.

It is interesting to note also that when, in 1906, the Western Packers Canned Goods Association met jointly with the Atlantic State Packers Association in the first approach to a national convention in the field, the two groups gave Dr. Wiley a respectful hearing and then passed a resolution endorsing pure food and drug legislation.

For these reasons and for the record, it should be remarked that the majority of sane, progressive businessmen *always* favored a rational regulatory law. Now, from the vantage point of 1946, let us look back down the years and trace the benefits of this law, its amendments, and its successor.

Act Gave Protection to Honest Manufacturers from Unfair Competition

Of its good effect upon the public health, there can be no doubt. Of its benefit to the consumer, simply in terms of quality, weights, and measures, there can likewise be no doubt. But it is upon its excellent consequences to the food industry and to industry generally that I would like especially to dwell today.

Food manufacturing was certainly not in its infancy in the 1900's. Canning, for example, began in Europe in 1810, was brought to this country by Underwood in 1820, and received great impetus, as did other forms of food manufacturing, during the Civil War. At the turn of the century, therefore, the food industry might be said to have been entering upon a lusty and somewhat unruly adolescence. In corner stores the cracker barrel, the dusty tub and bin, still prevailed, but canned and packaged goods, by sheer merit, were making headway against bulk products.

Fortunately for the food processing industry and for the country, the act gave honest manufacturers the protection they needed from unfair competition at the very time when a great new opportunity—and a great obligation—opened before them. The national economy, gaining momentum with every year since the industrial revolution, was rounding the corner into the machine age and into a new period of plenty and a standard of living such as the world had never seen. In this process, food manufacturing had a vital part to play. It has done so, and, in analyzing the reasons therefore, we find that possibly the most impressive single factor was this: *The conditions created by the passage of the act invited responsible businessmen to put real money into the food business.* Life suddenly became more precarious than ever for the fly-by-night payroll dodger whose practice it had been to make a quick clean-up in a single pack and vanish into thin air.

Freed from the competition of such as these, substantial businessmen staked their capital on the proposition that the consumer wanted, and would reward, *known quality.* They put their resources behind their guaranties and, as we have already remarked, they submitted readily to a law that was meant for the Medes as well as the Persians. And the food industry began to grow.

Growth of the Food Industry

In the decade between 1900 and 1910, capital investment in food and beverage manufacturing (exclusive of alcoholic drinks) rose from $909,000,000 to $1,700,000,000 and went on growing until today it exceeds $8,000,000,000. To me these are among the most dramatic industry figures that have ever been spread on the economic record. It is only so, however, when viewed in human terms. For what it meant inevitably was *a better life for millions of Americans*. It meant more, better, and less expensive food for the consumer; more and better jobs for workers; and it made a tremendous contribution to our national social progress.

In the home, packaged foods relieved the housewife of much of the burden of home canning and preserving. It enabled her to give her family a richer, tastier, more nutritious variety of foods. The extent to which green vegetables, for example, became a year-round staple at the family table is traced in the astonishing record of the consumption of canned green peas. In 1900 the total pack of this item was 2,500,000 cases and in 1945 it was 40,000,000 cases.

Now as to jobs. Records were poorly kept in the early days but those we have suggest that the maximum average employment in food manufacturing in 1900 was 416,000. Today it is about four times greater. No one knows for sure what the average annual wage in the industry may have been at the turn of the century but it was surely very small. By 1929 it had reached $1,503 and by 1943 it was $1,878, the latest available figure. Allowing for every possible change in monetary values, we behold therein another real example of the benefits of increasing industrial productivity. This has expressed itself also in terms of purchasing power, especially in food. Today's worker has to spend a far smaller proportion of his income for food than did his predecessor of 40 years ago.

Scientific Research by Food Industry

In these ways, I think, social progress is measured. Another great force in this transition was, and is, research. The industry's constant quest for more and better products was stimulated by the same factors that brought about its growth. This is a familiar story throughout all industries, of course. Today, the food industry alone expends $24,000,000 a year on scientific research. Without pausing to enumerate

its many accomplishments, I think it may safely be said that food research in recent years has already accomplished as many real miracles —in its *own* way—as any of those which the mechanical industries have promised us among their postwar projects. A simple but impressive example is that of tomato juice. In 1929 there was not enough of this new product to warrant inclusion in the industry's statistics; in 1931, nearly 5,000,000 cases were packed, and, in 1945, the pack exceeded 28,000,000 cases.

Growth of Food Processing Coincided with Development of Machine Age

It is in all these ways that food processing has made its contribution to the development of our industrial economy. We Americans began life as an agrarian people. In Colonial times 95 per cent of the population were farmers. The individual's chance to make or acquire any but the most rudimentary goods was very small.

Today only 15 per cent of our total working force is engaged in agriculture, yet our living standard is the best on earth. For this we can thank the machine. The great growth of food processing coincided with, and was necessary to, the development of the machine age. Transportation flung the population over new areas, pulled the people together in cities, and drew manpower to the mechanical industries, while at the same time the mechanization of agriculture freed manpower for other forms of production.

Vast Employment in Processing, Distribution and Sale of Food

Integral in the whole process was food manufacturing. The people in the cities had to be fed or the cities could not have grown as they did. Transportation was a factor of first importance, of course. Some of our most important food crops are grown largely in a single state or a handful of states; they have to be distributed. But that is not the whole answer; they must be preserved and stored for year-round, balanced use. Thanks to modern techniques of food processing and storage this task is now so smoothly performed that we are hardly conscious of it. Yet we find that the food industry has in turn generated vast employment not only in processing but in distribution and sales, so that

the three, taken together, constitute our largest single source of employment.

Blessings of Our Machine Economy

Lest we under-estimate the blessings of our machine economy, consider for a moment one of the nations that has failed to profit from modern industrial development. In China today, 80 per cent of the working population is engaged in an unsuccessful effort to produce an adequate supply of food for the nation as a whole simply because the Chinese are still struggling with archaic methods of production. As a consequence, the Chinese problem is that of sharing scarcities, rather than surpluses. This renders China, and every nation like it, the eternal prey of enemies from without and dissension within.

Because the United States followed the modern path to mechanization under the production-inspiring enterprise system, this country has achieved abundance, made itself industrially unbeatable in the military defense of democracy, and today is assuming 40 per cent of the task of feeding the hungry peoples of the earth.

Food and Drug Act Set the Stage for Progress in the Food Industry

It would be an exaggeration, of course, to attribute all of the food industry's splendid gains of the last 40 years to a single regulatory law. I think we have explored the many factors which naturally bear upon any development of the sort. Nevertheless, I believe sincerely that we must give the greatest recognition to the effect which the Food and Drug Act had in *setting the stage* for the progress of the industry.

All honor, therefore, to this law which made it possible for the honest and substantial manufacturer to throw his capital, his guaranty, his resources and his researches back of a constantly expanding system of food production and distribution; which in turn gave the consumer a constantly wider variety of constantly better foods at a constantly lower cost; and which made so material a contribution to the nation's economic progress, to employment and better living standards for all.

Honor to Dr. Wiley

All honor, too, to Harvey Washington Wiley, whose good crusade was carried forward to success because he knew and recognized real-

istically the viewpoint of others and because he made his appeal successfully to the best elements in the industry. All honor, too, to his successors in the administration of the Federal Food and Drug Act. Commissioner Walter G. Campbell compiled a splendid record in his long term in office. And I think there can be no doubt that under the present Commissioner, Dr. Paul B. Dunbar, the Food and Drug Administration will continue to shine forth among the bureaus of Washington as one of the most rationally, ably, and economically administered of all.

Conclusion

In conclusion, I can only echo the expression of one of the businessmen who, 40 years ago, went to Washington and, perceiving the potential benefits of the act, testified in its behalf by exclaiming that such a law would be a "grand, good thing." *[The End]*

PURPOSE OF THE 1906 ACT

"The purpose of the Act is to secure the purity of food and drugs, and to inform purchasers of what they are buying. Its provisions are directed to that purpose and must be construed to effect it." *United States v. Antikamnia Chemical Company* (1914) 231 U. S. 654.

The National Food, Drug and Cosmetic Law Instituted by the 1906 Act

ITS BASIC VALUE to DRUG INDUSTRY

S. DeWitt Clough

See also the address by James Hill, Jr., on the same subject. (Page 396.)

THE PHARMACEUTICAL INDUSTRY has prospered under the Federal Pure Food and Drug Law of June 30, 1906, as well as under the succeeding Federal Food, Drug, and Cosmetic Act of June 25, 1938, and such standardized, uniform, state food, drug and cosmetic laws which have since been enacted.

To prove this point I respectfully submit the following facts and figures:

The American Drug Manufacturers' Association was organized in 1907, slightly less than eight months after the passage of the original Pure Food and Drug Act, signed by Theodore Roosevelt on June 30, 1906.

The first meeting of the American Drug Manufacturers' Association was held at the Waldorf-Astoria Hotel on February 6 and 7 of that year. A trade journal, of that time, carried this comment of the meeting:

"The revolution which has taken place in the making of medicines during the past half-century was made manifest by a gathering held at the Waldorf-Astoria Hotel on February 6th and 7th. Here were gathered forty makers of medicine representing a capital of probably $50,000,000 whose annual output approximates $75,000,000."

Today, any one of a half-dozen firms, represented at that first American Drug Manufacturers' Association meeting, are now capitalized for more than $50,000,000 and the annual output of any two of these six firms now exceeds the estimated total of the entire group some forty years ago.

Mr. Clough is Chairman of the Board of the Abbott Laboratories

The present total production of the pharmaceutical industry is estimated now as fifteen times that of 1906.

The American Association of Pharmaceutical Chemists, now the American Pharmaceutical Manufacturers' Association, was organized also in 1906. At its sixth annual meeting, held in Cedar Rapids, Iowa, Mr. Bert L. Maltbie, then President of that group, had this comment to make in his annual address:

"That the enactment of the Pure Food and Drug Law and the Federal Harrison Anti-Narcotic Law was a good thing for the country we all agree. Pharmaceutical manufacturers in general and members of the American Association of Pharmaceutical Chemists in particular, respect the spirit as well as the letter of these laws."

As far back as 1912 the American Pharmaceutical Manufacturers' Association Executive Committee caused to be printed and distributed to each of its members, six cards measuring 16x24 inches, upon which, in letters one-half inch high, the following code of procedure was set forth:

"Honesty in business is a necessity. All service must be real. It is the policy of this company to be absolutely honest in its dealings with its customers, its creditors, its employees and its stockholders.

"All materials used must be of high grade, all formulas must contain in full amounts the written or given formula. All weights, measures and counts must be accurate and all book and other entries must be correct. There must not be any changing of formulas, or any false entries, or anything done, under any circumstances, not strictly in accord with the principles of honesty. Each one employed, from the highest to the lowest, must carry out in good faith the policy of his business which will not be changed under any circumstances."

Mr. Charles Wesley Dunn, who has served as General Counsel for the American Pharmaceutical Manufacturers' Association from its

inception, will agree with me, I believe, in stating that this code of conduct, written 34 years ago, conveys correctly the constant attitude of the industry as a whole, today and throughout the years.

The progress of the pharmaceutical industry during the past 40 years has been phenomenal. The records of growth, as well as the story of outstanding achievements, prove this to be a fact.

There are many good reasons for this remarkable growth. Here are a few factors, which in my opinion, have contributed to the present important position which this industry now occupies in our national economy.

In the order of their influence I will discuss the following broad features which have helped to make the pharmaceutical industry what it is today:

1. Research and control.
2. Confidence in and professional acceptance of pharmaceutical products.
3. Advance in medical knowledge, public health and nutritional education.
4. Cooperation with Federal, State and Municipal Governments.
5. Improved public relations.

All of these reasons for sound growth are related, rather closely, to the subject we are discussing today, as I shall endeavor to show.

Research and Control

During the fifty or more years prior to the passage of the Federal Pure Food and Drug Law the pharmaceutical industry was in a formative period without its present clear conception of the real value of individual and group research.

Comparative figures indicate that an average of less than one-quarter per cent, per dollar of net sales, per year, was spent in research and control 40 years ago. Today's surveys made by Mr. Dunn, and others, show that the present expenditures in the pharmaceutical industry for new product development, including fellowships, grants, chemical, pharmacological and clinical research, larger testing laboratories, expanded scientific staffs and increased research personnel, have mounted until these expenditures are now from three to five per cent of net sales, per year, and in some cases even more. As sales have mounted toward the billion dollar mark the ever-increasing ratio of research has reached astonishing totals.

Medicine has been moving with astonishing speed. Two world wars in 25 years have accelerated medical knowledge and scientific research to an extent hitherto unknown. The practice of medicine has changed so greatly and the doctor's armamentarium is so different today that even the pharmaceutical manufacturer himself, has difficulty in recognizing his specialty catalog of 40 years ago.

When I came into the pharmaceutical industry, some forty-four years ago, peroxide of hydrogen and tincture of iodine were the two largest-selling antiseptics. While these agents are still widely used there has been a constant and unending procession of new antiseptics, germicides, bacteria inhibitors, sulfa-drugs and antibiotics, including penicillin and streptomycin. Nor is this parade over by any means. In my opinion, medical research is still in an adolescent stage, but like a growing giant it is gathering greater momentum and power each year.

And a new infant is now on our doorstep. It is a war-baby. Since top-secret, wartime information has been released, the big problem is how the pharmaceutical industry can join with the universities in expediting the pharmacological, chemical, bio-chemical and bio-physical research of new substances such as radioactive isotopes, essential biocatalysts and other important radioactive agents which may well become our most important drugs of the future.

Cures for cancer and consumption, blatantly advertised in Frank Leslie's *Illustrated Weekly Newspaper* in 1856, may be, actually, just around the corner. In research terms this might mean from five to ten years.

I believe it is not an overstatement to state that the passage of the first Federal Pure Food and Drug Law in June, 1906, as well as the Food, Drug, and Cosmetic Law of June, 1938, did much to stimulate and encourage scientific research in the pharmaceutical industry. Certainly, it made closer control a necessity and raised manufacturing standards to new high levels.

And it may be added here as my second point that the administration of these laws during the past 40 years, plus the aid of other governmental agencies and the cooperation of the pharmaceutical industry, about which I shall speak later, has created in the minds of the medical profession, as well as in the consciousness of the laity, an increased confidence in the purity, the accuracy and dependability of pharmaceu-

tical products for the purposes claimed on the labels. This is particularly true since the amended act of 1938 went into effect. That this confidence is constantly becoming greater is proved by the fact that professional acceptance and recommendation of pharmaceutical products, advertised to physicians, now outweighs the influence of large sums spent in product advertising directly to the public.

Always there may be marginal manufacturers who are less concerned about research and scientific control than they are interested in sales volume and profits but I believe that this type of firm is rather rapidly passing out of the picture. It has been demonstrated, in the pharmaceutical field, that there can be no permanent success nor long-continued growth without a long-range research program and a well-organized, sufficiently-staffed control department.

Advance in Medical Education

The third growth factor, to which I have previously referred, is the advance in medical education, the widespread interest in public health projects and the newer knowledge being developed by nutritional research.

We are all familiar with the early crusades which paved the way for the passage of the pure food and drug laws and which contributed to the clean-up in the advertising and marketing of products, found to be of uncertain value or of dangerous character.

"The Great American Fraud" written by Samuel Hopkins Adams and published by P. F. Collier & Son, in 1905-06, is still remembered.

This early, atomic-attack on misleading advertising was followed by "The Propaganda for Reform" in the *Journal of the American Medical Association;* also, several editions of "Nostrums, Quackery and Pseudo-Medicine" from the same source. This was back in 1911, some thirty-five years ago.

As early as March, 1907, the first, paper-bound edition of *New and Non-official Remedies* appeared. This was published by the American Medical Association under the direction of the Council on Pharmacy and Chemistry of that Association. In that early edition it was admitted that "the more flagrant evils in the field of ethical or professional drugs had been mitigated or abolished."

Since that comment 35 years ago medicine has moved ahead with long strides as I have already stated. Medical education has made great progress and the impact of nutritional research has added new knowledge of very great importance. It may be that still greater developments in this field lie ahead. There is much educational work of a scientific nature which is still necessary to develop and prove the relationship between early malnutrition and the degenerative diseases of middle and old age. The large sums now being spent in this field for scientific research will, I believe, pay large dividends.

Many agencies are contributing to the wealth of expanding medical knowledge which is constantly reinforcing the basic foundations laid by the Pure Food and Drug Laws of 1906 and 1938. All of which augurs well for further advances in the pharmaceutical industry.

Before leaving this point I wish to call attention again to the favorable editorial comment of the *Journal of the American Medical Association* of August 4, 1906, on the passage of the first Federal Pure Food Law. This comment closed with the last line: "Uniform State Pure Food and Drug Legislation is now needed." Almost every year since that time the pharmaceutical industry has advocated by resolutions such uniformity in our state laws.

Cooperation

In introducing my fourth point on Cooperation with Federal, State and Municipal Governments I quote from an educational advertisement which appeared 26 years ago under the somewhat dramatic headline, "Cave Life or Civilization":

> "Civilized man is distinguished from the cave-man by his habit of cooperation.
>
> "The cave-man lived for and by himself, independent of others but always in danger from natural laws. To the extent that we assist one another, dividing up the tasks, we measure our capacity for production and attain the advantages of civilization.
>
> "Our Government is entrusted with the task of regulating, controlling and protecting a hundred million people. It is to the advantage of everyone that the government shall be so efficient that all of us may perform our duties under the most favorable conditions.
>
> "Interdependence means civilized existence."

This sentiment, expressed over twenty-five years ago, might well apply today to the relationships between the Food and Drug Administration and the pharmaceutical industry.

In January, 1945, Dr. F. O. Taylor, Chairman of the Combined Contact Committee, submitted an excellent report to the Executive Committee of the American Drug Manufacturers' Association, as well as to the Officers of the American Pharmaceutical Manufacturers' Association, covering a brief survey of the origin of the Contact Committee, its development and present activities. I quote from this report as follows:

"At the annual meeting of the American Drug Manufacturers' Association at the Hotel Biltmore in New York, April 7-10, 1924, Dr. George W. Hoover, then Chief of the Division of Drug Control of what at that time was the U. S. Bureau of Chemistry, delivered an address concerning the condition of drug products as this division had found them on the market (American Drug Manufacturers' Association Proceedings, 1924, pages 125-132). He referred particularly to various items not standardized by either the U. S. Pharmacopoeia or the National Formulary, and presented data concerning the bad conditions which had been found. Among other things he said:

" 'It is believed that most of the pharmaceutical preparations on the market are satisfactory in every respect. It is evident, however, that there is need of vast improvement in some quarters. You as drug manufacturers and we as control officials are therefore vitally interested in having all pharmaceutical products upon the American markets above reproach. The question then naturally arises as to how the unsatisfactory conditions are to be remedied. It may be that this Association can further extend its influence and adopt whatever additional measures seem best for correcting any unsatisfactory conditions that exist within the industry as a whole. Corrections made by the industry itself are more desirable than recourse to other means.' "

In an informal conversation with Dr. Hoover, after the talk, Dr. A. S. Burdick, then President of the American Drug Manufacturers' Association (and Abbott Laboratories), suggested the formation of an industry committee which would collect data on pharmaceutical products and submit these to the Bureau of Chemistry. In the course of this conversation, the structure of a "contact committee" was evolved.

The assistance which Dr. Hoover requested, on behalf of the government, at that time came very definitely within the scope of the stated purposes of the American Drug Manufacturers' Association. Following is a quotation from the Preamble to the American Drug Manufacturers' Association Constitution, which remains today as it was then:

"WHEREAS, It is desirable, in the manufacture and marketing of such products, to maintain the high standards generally observed by manufacturers individually during many years past; to encourage and promote still greater achievements; to insure to individual members the just and proper reward of initiative, discovery and invention; to prevent fraudulent practices in the drug trade; to encourage the lawful enforcement of sound drug legislation, and effect official observation of the fundamental law of the land; to prevent the subversion of law to factional purposes; to amicably adjust differences; to advance uniform and just drug legislation; and in other lawful

ways to promote the welfare of and fraternity among those engaged in the manufacture of therapeutic agents for the use of the medical and allied professions."

About this same time Dr. Hoover gave a similar address before the American Pharmaceutical Manufacturers' Association and made a similar appeal to them.

Pursuant to these addresses and discussions in the respective Executive Committees of the two Associations, committees were appointed to work in cooperation. Dr. Burdick, then President of the American Drug Manufacturers' Association, appointed the following committee:

Carson P. Frailey
F. W. Heyl
A. Homer Smith
Frank O. Taylor
J. Paul Snyder—Chairman

Dr. Snyder was also at that time Chairman of the Scientific Section and it was distinctly recognized that this was to be a scientific and technical committee.

From the American Pharmaceutical Manufacturers' Association Mr. Foy, then President, appointed:

A. D. Thorburn
C. E. Vanderkleed
J. Allen Tailby
R. Lincoln McNeil—Chairman

The Combined Committee subsequently met and elected Dr. Snyder and Mr. McNeil as, respectively, Chairman and Secretary of the Combined Committee.[1]

The first report of the Contact Committee was presented at the fourteenth Annual Meeting of the American Drug Manufacturers' Association in New York, April 20-23, 1925, (Proceedings American Drug Manufacturers' Association, 1925, pages 156-163). This is particularly interesting as it indicates some of the foundation work laid by conference with the food and drug officials.

[1] The original Joint Contact Committee of the American Drug Manufacturers' Association and the American Pharmaceutical Manufacturers' Association had two Co-Chairmen, Dr. John Paul Snyder, and Mr. R. Lincoln McNeil. Dr. Vanderkleed acted as Secretary. This arrangement was effective until 1928 when Mr. McNeil was elected President of the American Pharmaceutical Manufacturers' Association. Dr. Vanderkleed was then made Chairman of the American Pharmaceutical Manufacturers' Association Committee and Secretary of the combined committee under the leadership of Dr. John Paul Snyder.

At the same meeting Dr. Hoover again spoke very briefly, as follows:

"I may say that the Bureau of Chemistry and the officials of the Department are very much pleased with the work of this Committee. The Committees of the two associations, it seems to us, have approached this subject in a very broad-minded manner. They have conducted the work on a high plane, and doubtless it will result in much benefit to the public, as well as to the industry itself."

Gentlemen, this is a very brief summary of how a big job was well started 22 years ago. And the work still goes on. I believe you will agree that it is an excellent example of how industry and government can cooperate constantly to the best interests of both and for the welfare of all the people.

The record speaks for itself. And the records of industry cooperation during the first and second World Wars, both with the armed forces and governmental agencies, will always remain bright pages in the history of the pharmaceutical industry.

Public Relations

And now a word in closing on the subject of public relations, my last point. Dr. Wiley began to talk and write about the need for pure food and drug laws in 1879—the year Thomas A. Edison discovered the incandescent light. And we know it was not until 27 years later that his dreams came true and the first Pure Food and Drug Law was passed. This law has now been effective for 40 years and has been further reinforced by the amended act of 1938.

The effect upon public morale of these laws has been most salutary and the basic value to the pharmaceutical industry cannot be calculated in dollars and cents alone. The present prestige of ethical pharmaceutical products is a tribute to research, to dependability, to education, to cooperation, to public relations, and to the Food and Drug Administration, to whom we extend congratulations on this, their fortieth anniversary.

[*The End*]

The National Food, Drug and Cosmetic Law Instituted by the 1906 Act

ITS BASIC VALUE to DRU

See also the address by S. DeWitt Clough on the same subject (Page 387.)

SINCE THE BEGINNING OF TIME, man has sought to cure or relieve his ills through the use of preparations, decoctions, concoctions and medicines which either he prepared himself or others prepared for him. The art of medicine making has improved over the ages, as have the healing arts; but greater advances have been recorded during the past 40 years than in all of the preceding centuries of history.

These 40 years mark also the life of our Federal Food and Drug Laws which came into being on June 30, 1906, through the signature of President Theodore Roosevelt on this country's first pure food law. And it is more than a passing coincidence that the four decades since the law's enactment have been marked by giant strides in the art and science of compounding medicines on a commercial scale.

Science Has Become an Integral Part of Business Function

It happens, also that this period has seen science become an organized, integral part of business function. Whereas it had previously been the concern primarily of individuals, struggling alone or supported by pittances from public spirited men or institutions, today science is as much a part of the daily living of business enterprise as manufacturing, selling or any of its other manifold functions.

This combination of government regulation in the true meaning of the public interest and of scientific approach has enabled the manufacture of medicines to reach the crest of responsibility it now occupies. It is perhaps as much a tribute to the present-day enlightenment of business enterprise as to the food and drug laws that representatives of

U NDUSTRY

James Hill, Jr.
President, Sterling Drug Inc.

Blackstone Studio Photo

the several industries under the laws' jurisdiction are here today, with the full approval of their colleagues, to pay homage to legislation that has won universal respect.

Comment on Dr. Parran's Address

I listened with great interest to Dr. Parran's address and noted especially his observations respecting radio and newspaper advertising of drug products.

We in the drug industry have not been unmindful of our obligation properly to represent our products to the consuming public. A dozen years ago the Proprietary Association of America formulated an advertising code, and two years ago this code was revised in the light of modern thinking. A dozen years ago, also, there was formed within the Association an advertising review service; and members of the Association, representing 80 to 85 per cent of the packaged medicines manufactured in this country, can submit their copy to this service for review and criticism. More and more members have done so over the years. Indeed, in 1945, no less than 15,000 separate pieces of advertising copy were thus submitted.

In a further effort to raise the standards of our advertising, the Association, through its executive vice president, Dr. Frederick J. Cullen,

a former member of the Food and Drug Administration staff, proposed the formulation of copy review committees in cooperation with the newspaper, radio and magazine media. This proposal is still under consideration by the media, but we are satisfied that its acceptance by the media will result in still further raising the standards of advertising.

Pure Food Law Opposed at First

That the pure food law, when originally proposed, should have been strenuously opposed, is hardly surprising. Few important changes from the accepted norm, few deviations from the comfortable routine of thinking and living, have been achieved without resistance. This has been the history of change in all countries, in all times. The industrial revolution which unchained man from the serfdom of pitifully scant production was bitterly resisted by the very masses it was to help because they could not understand its long range implications. Even today large groups with a vested interest in current tools seek to obstruct the road to progress through invention, if such discoveries would seem immediately to reduce their earning ability.

Back in 1906, to be sure, a few manufacturers joined with consumers and others in advocating the pure food laws, but many more looked upon the proposed legislation as an instrument of ruin for their industry rather than as a social landmark and an economic boon. Again in 1938, some manufacturers opposed the Food, Drug, and Cosmetic Act, but this time many more manufacturers had come to recognize the salutary effect of the 1906 act and worked actively in securing the passage of the act now in effect.

Food and Drug Act Now Supported by All

To those still alive who helped bring the 1906 act into being and to the many others who have given the statutes substance, the fortieth anniversary commemoration must be a cause for real gratification. And it is worthy of note that the tribute comes at a time when men everywhere have sharp differences as to the role of the state in the affairs of men. Throughout the world there is clamor for more government regulation, for more administrative agencies, for a greater degree of individual security through the state. At the same time, in those areas where democracy continues to have real meaning, a large body of opinion holds that less of the state in the conduct of our lives is necessary to

the realization of true liberalism. Yet there is no difference as to the wisdom of the statutes pertaining to foods and drugs. They have not only accorded the consumer a high degree of protection, they have also helped the drug manufacturers to gain their present stature.

Provisions of 1938 Act

The 1938 act, as the logical outgrowth of the first pure food law, prohibits the sale in interstate commerce of products that are adulterated, misbranded or dangerous to health; establishes minimum standards of strength, quality and purity for many drugs, and sets up specifications for the labeling of foods, drugs, cosmetics and therapeutic devices.

The Modern Manufacturer of Medicines

The modern manufacturer produces medicines, not on the kitchen stove on which a Shropshire housewife brewed the first digitalis, but in a plant that meets the exacting standards of the times. The products themselves, whether they be pharmaceuticals, labeled and advertised for use by the physician or on his prescription, or packaged medicines that are adequately labeled so as to permit use in self-medication for minor ailments, are the best as to quality, efficacy and uniformity that have been made available to man since the beginning of time. Into these products go the laboratory and clinical knowledge which a scientific age has produced, including the research information to obtain which the drug manufacturers spend more than $10,000,000 a year, careful controls guarding the manufacturing process and laboratory testing of ingredients and of the finished preparations. Into them also goes the makers' acknowledgement that they have a responsibility to the public as well as to their stockholders. Perhaps there are a few who still are out of harmony with the spirit of the times, but they are no more representative of a great industry than any law violator is of a nation's citizens.

Changes in Medicines and Medical Practitioners

What a remarkable change has been wrought over the centuries in the products which are today in every family medicine chest. For almost 200 generations, going clear back to the ancient priests who wrote the prescriptions of their day, most of the products available for the

relief and cure of disease reflected a mixture of magic and superstition as well as of honest empiricism. Thus, 5000 years ago the Chinese made valuable use of a substance known as *Ma Huang*, which we now know contained ephedra as its active principle. But the ages have seen lizards' blood, swine's teeth and snake oil. Today we have an imposing array of valuable medicinal preparations, produced by men dedicated to the manufacture of medicines in accordance with the high standards of science and of the law which we here honor. Likewise, the witch doctors and blood-letting barbers of another day have been supplanted by physicians highly trained in the practice of scientific medicine.

Wisdom of Food and Drug Administration

As to the statutes to which we pay tribute, they are not unique in the worthiness of their objectives. Many other statutes can be found, whose preamble cites equally laudable public purposes, which have failed to win unanimous tribute or to serve the public interest with equal effectiveness. The difference lies in the administration of law. The statutes with which we are here concerned were made to work through the patience, wisdom, courage and justice of the men who were and are charged with its administration. These men were not intent on achieving new heights of power through tortuous interpretation of the act or the misapplication of social or economic theory; rather they stuck to the lines of the statutes, administering them strictly. We who manufacture medicinal products have frequently found ourselves within the precincts of the Federal Food and Drug Administration. Our viewpoint and those of the officials have at times differed. On occasion, because of the normal hazards of our business, we have been cited for violations and sometimes haled into court. Yet in my years in the business, I have rarely heard a charge that these officials were unfair or capricious. That is, indeed, a welcome contrast from the experience of business men with some other governmental agencies and their personnel.

Accordingly, while making public acknowledgment to the law for its value to the industries regulated by it, as well as to the public, let us acknowledge our debt to the men who have made that law work so brilliantly. May we hope that their successors will carry on in the tradition established over 40 years and maintained to this day, to the end that those who will commemorate the law's hundredth anniversary may still call it a good law. [*The End*]

The National Food, Drug and Cosmetic Law Instituted by the 1906 Act

ITS BASIC VALUE to COSMETIC INDUSTRY

H. Gregory Thomas

"IT IS LATE, it is hot, and you, gentlemen, may be tired, but I beg of you to grant me your patience a little longer". So, on a day in late June, just forty years ago, Dr. Harvey Washington Wiley, great proponent of pure food and drug legislation, might have spoken to those who were later to enact the first Pure Food and Drug Act of the United States.

The files of the great newspapers of the year 1906 show strong popular and editorial support for Dr. Wiley and his long struggle for enactment of a pure food and drug law. Industry opposition by those the papers describe as "medicine men" is held up to contempt, but lobbies were powerful, and in the late days of June it looked as though Congress might adjourn without taking the favorable action which the enlightened public was demanding. Dr. Wiley fought tenaciously on, and with the aid of the President and the Cabinet and leading proponents of the bill, it carried all opposition before it. It was enacted, to go into operation on January 1, 1907.

Perfumery and Cosmetic Industry Welcomed 1938 Act

It is not the purpose of my paper to give the history of the original Pure Food and Drug Law, but since we are today rendering to it the homage of this meeting, which it so richly has earned from grateful consumers and worthy industry alike, I must show how the perfumery and cosmetic industry was to welcome with enthusiasm, in 1938, the

H. Gregory Thomas is Vice President of Bourjois, Inc.

present Federal Food, Drug, and Cosmetic Act, a law which we might not have enjoyed had it not been for the years of effort and the deep faith of the framers of the act of 1906.

From this platform this afternoon you have heard the addresses of high government officials and of leading members of the food and drug industries. These gentlemen have paid tribute to the fathers of food and drug legislation. I stand before you in representation of the cosmetic industry, and you may wonder what a member of my industry can have to say about the act of 1906, a law which fails to make any mention whatsoever of the products we manufacture and sell. I believe that it is fitting that we should be represented here for we now enjoy to the full the protection of the Food, Drug, and Cosmetic Act of 1938. We worked with the late Senator Copeland from the outset to its enactment, and we recognize that the act of 1906 provided us with the legislative antecedent which prepared the way for the present law.

History of Cosmetic Legislation

A short review of the history of cosmetic legislation has most recently been presented in the *Food Drug Cosmetic Law Quarterly*, Volume 1, pp. 61-65, by Hugo Mock, the distinguished counsel of the Toilet Goods Association, long known as a leading authority on the subject. Although the history of perfumes and cosmetics is as old as the history of mankind, Mr. Mock has been unable to find mention of the word *"cosmetics"* in legislation prior to a curious bill proposed to the English Parliament in 1770. The language of this proposal strangely

enough, but perhaps naturally for that riotous period, seeks not to control the manufacture or sale of cosmetics, but rather to protect Englishmen from being lured, unwary, into matrimony by the use of such instruments of the devil as scents and high heeled shoes, cosmetic washes, artificial teeth, paint, bolstered hips, and hoop skirts. The penalty imposed on virgins, maids and widows alike, for stooping to such trickery, was the same as that for crimes of witchcraft.

You might think we had come far by 1906. In many ways we had, but in the general acceptance of cosmetics, and the regulation of their manufacture and sale, the silence of the legislation of 1906 is even more eloquent than the strange conceptions of 1770.

"Hippopotami and Canary Seed!"—that is the headline of an article which appeared in the New York *Daily Tribune* of October 1, 1906, one of the many discussions of regulations which were then being elaborated. This article seriously praises the thoroughness of a law which will guarantee genuine timothy hay for the hippopotamus in the zoo and non-adulteration of bird seed for the household pet. Yet no mention is to be found anywhere of the products of my industry—cosmetics. Why? That is one of the things I shall try to explain this afternoon.

Cosmetics Were Objects of Puritanical Disapproval

There must have been some reason why there was no mention of cosmetics in the great exchange of written and spoken material that preceded the enactment of the law of 1906. True, in the early days of the century, cosmetics were still the objects of the Puritanical disapproval which had risen to such heights in the Victorian Era, and which had not yet been dissipated by the brilliance of Edwardian Europe. Cosmetics were honorable adjuncts of the stage; other circles in which they were used were not even mentioned in polite society.

America, a new land of pioneers and their children, had little in common with the court life of the glamourous past, where history shows the use of cosmetics to have flourished. The American ideal of beauty was the healthy outdoor girl. The Victorian idea of the pale damsel in hoop skirt or crinoline seemed almost as remote as the powdered and beribboned elegance of Versailles.

Further, we were at the eve of the great day of woman's emancipation. America was to admit women to a place in the world of business,

politics, science, the law; and these women must look their best at all times, and at all ages, to compete in our competive society. Thorsten Veblen, in his profound analysis *The Theory of the Leisure Class* clearly shows how man had earlier dominated women's vanity and women's fashions. Now we come to the era when women were to earn their own money and spend it as they chose. Their choice was to look better—with the aid of cosmetics!

Growth of the Use of Cosmetics

The use of cosmetics grew through the harrowing days of the Great War, and on through the luxurious Twenties, with women ever demanding more and more lasting performance on the part of their beauty aids. A few, and I am proud to say a very few, unscrupulous manufacturers allowed themselves to be tempted by the black brilliance of dangerous paraphenylene-diamine hair dyes, by the use of harmful bleaches to lighten the complexion. Such men escaped the control of adequate laws because they did not exist. There was no other way to restrain them. The great cosmetic companies, and the mass of consumers alike suffered, and the whole industry was subjected to attack because of the misdeeds of a few avaricious men operating to the general detriment.

No Regulation of Cosmetics Applied Externally in 1906 Act

True, the act of 1906 had forced the removal of such beauty products taken internally as Campbell's Arsenic Wafers, said to lighten the complexion, but at the terrible cost of cumulative poisoning. There still was no regulation of cosmetic preparations to be applied externally.

Relief to all, safety for consumer and reputable manufacturer alike, lay in the new law which was to regulate cosmetic production, as the old act had protected food and drugs.

A few manufacturers may have worried at the thought of government intervention into their business, a few believed that they would suffer at the hands of witch-hunting officials, but with these few exceptions the industry stood to a man behind its trade association in relying on a fair deal from the Food and Drug Administration.

Cosmetic Industry Needed Protection of a Federal Law

When proposed, the Federal Food, Drug, and Cosmetic Act met with immediate and favorable response from the industry I represent. It was my privilege to work with Charles Welch, the late Secretary of the Toilet Goods Association, and with Hugo Mock, and with Steve Mayham, now Executive Vice-President of the Toilet Goods Association, then a principal champion of the proposed law in his capacity as editor of a leading trade publication. All these men, and so many others truly representative of our industry, knew we needed the protection of a Federal law.

The great and fast growing cosmetic industry welcomed Federal legislation in 1938 for a number of reasons. There could be no other answer to the crescendo of ill-informed baiting by self-styled "consumer" organizations. Paid counter-publicity to the extremist accusations of the disciples of the "guinea pig" school would not free the public from the apprehension of being drawn into a new "Chamber of Horrors."

An industry such as ours, selling aids to good grooming, to a better appearance, contributing through its products to that intangible quality we call charm, must be ever unusually sensitive to all manifestations of consumer opinion.

Cosmetic Industry Is Grateful to Food and Drug Administration

Recently, as from time to time in the past, a certain type of cosmetic product has been singled out for scathing condemnation by a professional spokesman for a large professional organization. In past years, manufacturers weighed such statements carefully, with due consideration of the source from which they emanated. Today, when the Food and Drug Administration can find no cause for taking properly qualified action, both industry and consumer can feel that harmful products cannot, and will not, long be sold. Sweeping condemnations, which are not founded on the proofs of scientific experimentation, today arouse only that scepticism and resentment which their proponents so richly deserve.

International law has failed through lack of sanctions. Domestic laws can also fail when sanctions are applied ruthlessly or loosely; both will ultimately destroy the law itself. It should always be a pride to our government, and to the Food and Drug Administration, that its

field officers, its inspectors, have mirrored the high purpose and integrity of their Washington superiors, and have so often led manufacturers through the technicalities of the law and its regulations to full compliance, in the interest of the consumer and the improvement of the product.

We inaugurated an era of mutual confidence and mutual help. I stand here today to say, on behalf of the cosmetic industry, that we are not only satisfied, but grateful for the way in which our problems have been met and solved.

Cosmetic Industry Cooperates with Food and Drug Administration

The Cosmetic Division of the Food and Drug Administration, established for the specific purpose of regulating products in the toilet goods field, has always enjoyed the fullest cooperation of the trade association for the cosmetic industry. In particular, there has been, in the past, the matter of the elaboration of regulations, procedures, and tolerances in the certification of coal tar colors, which are so essential to so many cosmetic preparations. Throughout the hearings on the proposed color regulations, a committee of technicians representing the coal tar color industry and the cosmetic manufacturers worked closely in submitting views and methods which were of material assistance to the officials of the Food and Drug Administration. Today, and in the past years, the Scientific Section of the Toilet Goods Association, grouping the leading scientists and technicians of our industry, have made their findings known to the Cosmetic Division, and have thus contributed a wealth of scientific data on cosmetic products and their preparation which had never hitherto been available.

Administrative Interpretations Aid Cosmetic Industry

The stated and continuing policy of the Food and Drug Administration to give industry the benefit of administrative interpretations of the present law, in its effect on the legality of the composition or processes of production of a given cosmetic, has been most helpful to us, and we hope such a policy will continue in years to come.

The informal decisions of the Administration on new or borderline questions, which have been made available to industry members through letters and documents, which can be seen at several offices of the Food

and Drug Administration, have also been avaluable source of guidance to manufacturers, and one which in turn facilitates compliance with, and enforcement of, the law,

We have had occasion to note that it is the policy of the Food and Drug Administration

"to avoid interference with the development or adoption of new products, or processes that represent genuine advancements, and that are, therefore, in the interest of consumers."

I have here quoted Mr. Crawford, the Associate Commissioner of Food and Drugs, whose progressive attitude reflects that of the Administration when he states in a recent article,

"Food and Drug Legislation is not static. It should not be so. Scientific and technical advances in production and distribution, the creation of new and improved products, and the shifting patterns of consumer demands, create new problems that can be met only by legislative action." [1]

We, of the cosmetic industry, subscribe to this view of a law that has grown, and will continue to grow with our industry.

Cosmetic Industry Favored Passage of 1938 Act

The cosmetic industry had not been considered of sufficient importance in 1906 for its products to be given the protection of the law. One of the late Senator Copeland's favorite projects in the early Thirties was to bring cosmetic products within the scope of a new law. From the first hearings on the bill, which was to result in the enactment of the law of 1938, the large majority of the cosmetic industry went on record, through its counsel, as favoring the proposed legislation. This constructive and progressive attitude of the toilet goods industry continued through the years of hearings and in the several stages of the elaboration of the final Copeland Bill.

A Federal Law Was the Only Acceptable Type of Law

I have said that a Federal law was the solution; it was also the only acceptable type of law. Individual laws, adopted by a number of states, with separate requirements perhaps—almost certainly with conflicting provisions—would have imposed insurmountable obstacles to the orderly expansion of manufacturing and distribution on a national scale. It

[1] *Food Drug Cosmetic Law Quarterly*, Volume 1, p. 18.

has wisely been said that cosmetics are not regional in their nature—they are as universal as packaged foods or drugs, and national control by a national agency, under a national law alone, seems to guarantee security and successful enforcement.

The act of 1938 was the right kind of legislation, and it is to be hoped that the several states will enact Food, Drug, and Cosmetic Acts in exactly the same terms.

An industry, whose volume in 1900 did not exceed 5 million dollars, but which by 1914 had grown to 39½ million dollars, and had expanded by 1938 to 366 million dollars, pays due tribute to a law, under the fair and efficient enforcement of which, it has continued to flourish to the point where in 1945 it had reached the impressive volume of 659 million dollars in the service of its consumers.

[*The End*]

LACK OF COSMETIC REGULATION

". . . During all these periods which witnessed the organization and development of State Boards of Health and the appointment of state chemists, no mention is ever found either in New York State or any other state statute that I know of, of cosmetics or toilet preparations. This is not so strange as it might appear at first glance, for I beg to remind you that in 1850 or thereabouts the installation of the first bathtub in Cincinnati reputedly caused a local scandal, and it is in the memory of many of you that the use of face powder and lipsticks in the United States, at least, was at one time largely confined either to the stage or to the world's oldest profession." Hugo Mock in the *Food Drug Cosmetic Law Quarterly*, Volume 1, p. 62.

The National Food, Drug and Cosmetic Law Thus Instituted

....ITS SOCIAL AND ECONOMIC ASPECTS

Watson B. Miller, Federal Security Administrator

AN OCCASION SUCH AS THIS is both stimulating and encouraging. It causes us to pause and look back along the road we have been traveling. From a perspective similar to that of historians of the future, we examine a forty-year period of evolution in one of our most important phases of public welfare.

Progress, in General, Has Been Gratifying

Retrospection is not always pleasant nor profitable. Certainly a review of nation-wide operations designed to improve our food, drug and cosmetic supplies does not—in some details—present a wholly satisfactory picture. But progress in general has been gratifying. It gives firm support to our earnest hopes for the future. We find cause for renewed faith in a confirmed national tradition—that democratic self-government is capable of meeting the diversities and changes of every era.

It would be unrealistic to contemplate developments in the field of food, drug and cosmetic control apart from the general advance in social legislation. The times we are considering have seen vast social revolution. The functions of government have had to be adjusted to meet unprecedented problems created by these changes.

National Legislation to Promote the General Welfare

One of the honest objections to passage of the Food and Drugs Act of 1906 was that it was an infringement of the rights of the individual

states. That is an exception which has been taken to many other types of legislation before and since that time. The underlying problems have been much the same. The states have been as reluctant to give up any part of their authority in the interest of building a unified nation as nations are today unwilling to relinquish supreme sovereignty for the purpose of creating a more harmonious world.

Reasons for enacting a Federal food and drug law were much the same as those for other types of national legislation designed to promote the general welfare. As means of communication increased, state boundaries became little more than lines on the map. Varying standards and regulations of 48 legal jurisdictions when applied to products in interstate commerce presented similar problems to those encountered in the fields of social insurance, public assistance, education and health—to name those interests with which the Federal Security Agency is concerned.

The laws of a democracy cannot be static. Their purpose is to further the welfare of the people they govern. As new forces and new needs arise, our laws must adjust so as best to serve that purpose. Social legislation must be built upon the basic and cardinal principles established by the founders of this nation. It must serve the aim of creating conditions which will afford maximum freedom for the individual, consistent with just and equitable relations with others. It must protect the individual from malign forces within the national economy and from such other forces as it can control. It must turn the resources of the nation to the benefit of the individual.

Food and Drug Act Protects Both Producers and Consumers

President Lincoln once defined as

". . . the legitimate object of Government—the doing for a community of people whatever they need to have done, but cannot do at all or cannot do so well for themselves in their separate and individual capacities."

The Federal Food, Drug, and Cosmetic Act represents fulfillment of this function. In a case in a Connecticut District Court, the Judge's charge to the jury included this:

"It is the purchasing public, the ultimate consumer, whom the provisions of this law are primarily intended to protect. The law is not made for the protection of experts, but for the public, that vast multitude, which includes the ignorant, the unthinking, and the credulous, who, in making purchases, do not stop to analyze, but are governed by appearance and general impressions."

In his message to Congress recommending reform in food and drug legislation on March 22, 1935, President Roosevelt said:

"The honor of the producers in a country ought to be the invariable ingredient of the products produced in it. The various qualities of goods require a kind of discrimination which is not at the command of consumers. They are likely to confuse outward appearance with inward integrity. In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently and producers are handicapped in any attempt to maintain higher standards."

The Food, Drug, and Cosmetic Act serves to protect equally the large majority of manufacturers whose honest desire is to maintain ethical business standards and further the welfare and respect of their customers through the quality of their products. Such manufacturers work in cooperation with government officials in support of effective administration of the law.

The 1917 Annual Report of the Bureau of Chemistry—now the Food and Drug Administration—includes this comment on other benefits to industry from the law:

"The act has been one of the influences which has helped to draw competitors together into associations like the guilds of the Middle Ages, associations shorn of the special privileges which the ancient guilds often enjoyed. These associations have come to understand the value of constructive work and some of them devote considerable sums annually to experimental research designed to solve the technical problems with which the industry is confronted. Thus, there is made available to the small manufacturer scientific assistance which would ordinarily be obtainable only by large corporations maintaining their own staff of investigators. Since the Bureau of Chemistry has always regarded it as its duty not merely to report violations of the law but also to prevent violations by constructive work intended to improve methods of manufacture, it cooperates actively with such associations of manufacturers. Such cooperation by the various Government agencies is bound to exert the profoundest influence on the country's industrial and social development."

Democracy in Action

I believe the association of government and industry in the interest of upholding high standards in our food, drug and cosmetic supplies is a fine example of democracy in action. Here government has successfully drawn the thin line which marks the necessary restrictions upon free enterprise in the interest of the collective welfare. I am sure that the controls exercised by government have in no way served to bear out the fears of manufacturers who fought against this legislation and delayed

its enactment for many years. The controls have not put the manufacturers out of business.

As with the fears of industry, so with those of the states. The government has not taken over their powers. With this, as with other social legislation now in effect, a closer partnership has been established between the states and the Federal government—each strengthening the other. Scientific procedures developed in state food and drug departments have been of help to the Federal Food and Drug Administration which in turn gives aid and counsel to the state departments. I know that the fine men who staff the Federal Administration stand always ready to give aid in any way possible to the states or to manufacturers in the interest of better law enforcement and higher quality products.

No Way of Measuring Results of Food, Drug, and Cosmetic Legislation

There is no way of measuring the results of our food, drug, and cosmetic legislation. It cannot be done with statistics. We cannot say how many lives have been saved because manufacturers are prohibited from selling injurious products. No one can even roughly estimate what the public has been saved economically through prohibition of fraudulent labelling and deceptive packaging.

What we do know is that this law, along with other social legislation, has served to contribute to our faith in our government. It has built up a respect for the integrity of our commercial institutions. It adds to our belief in the fairness and justice to be found in a representative form of government. It demonstrates the virility of our indefinable fusion of popular government and free enterprise.

The fact that we are assembled here to pay tribute to the enactment of this law is, I believe, indicative of the respect paid to it in the thoughts of all those concerned in its immediate operations. We in the government are proud to share this occasion with you members of the legal profession, who engage in interpreting the law for industry, and with you representatives of the manufacturers who must conform to its mandates, and with you members of the consumers' groups who are sponsoring this evening's meeting. I believe I may be permitted to surmise out loud that our invitation to be present is probably a tribute to the administration of the law. I believe *I* may say this because credit for

its administration can go only to Dr. Paul Dunbar, the Commissioner, and his predecessor, Mr. Walter Campbell, and to the loyal and able staff of the Food and Drug Administration.

We shall all draw inspiration from these metings. It is good to look back and realize the very material gains that have been made in the last forty years. We face the future with renewed faith and determination.

[*The End*]

MEETING INADEQUACIES OF 1906 ACT

"This [the 1938] act seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906, as amended (U. S. C., title 21, secs. 1-15). That act is popularly known as the Wiley pure-food law, because that great pioneer in pure food and drug legislation, Dr. Harvey W. Wiley, led the fight for its enactment.

"While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions." Report of House Committee on Interstate and Foreign Commerce. House of Representatives Report No. 2139, 75th Congress, April 14, 1938.

The National Food, Drug and Cosmetic Law Thus Instituted

The CONSUMER'S VIEWPOINT . . . .

Kathryn H. Stone . . . First Vice President of the National League of Women Voters

BEGINNING IN 1920 when the League of Women Voters was organized in Chicago, as successor to the National Women's Suffrage Association, our organization has always been concerned with the protection of the consumer through government. Through its department on living costs, the League in its earliest years had an interest in the 1906 law of food and drugs.

Long before woman was given the vote in this country, her position as a housewife had become quite different from that she had occupied a hundred years before. Instead of producing in her garden and in her kitchen all the food her family consumed, she was buying it from the supplies which the country's budding productive genius had begun to make available. Instead of brewing mullen and senna tea from leaves gathered in the field to treat her children for various "tummy aches" and giving them sulphur and molasses as a spring tonic, she was beginning to rely on her druggist and her doctor. The more she went outside the home for these services the more she became acutely aware of her inability to look through cardboard boxes, and through tin cans to see what kind of food she was buying, or to analyze chemically the drugs she purchased for home medication. Gradually she began to want government to make certain decisions for her and to let her know what those decisions were.

The newly organized voters undoubtedly brought with them into the League only a vague knowledge of the food and drug act. But

"We have a law and an administration of that law that protects me as a consumer from inferior products."

gradually in small numbers they became aware that although it did much for them as consumers, it did not go far enough. Thousands of bottles of Lydia Pinkham Compound were consumed for various nervous disorders and pains before women realized that they were paying thousands of dollars a year for only a mild vegetable tonic. In communities here and there, news leaked out of the death of an overweight woman, and evidence pointed to a dangerous drug present in a patent reducing medicine. Some place else a friend of someone developed a bad case of anemia, or met death, from headache pills (found to contain amidopyrine and barbiturates). Still another place someone became blind after using a certain eyelash preparation. Here and there a few people became aware of the need for a better law to protect citizens from such calamities as blindness by cosmetics, death by untried drugs, and robbery of the family pocketbook by synthetic food products with fancy names but no list of ingredients. The law was also needed to safeguard the interests of the honest and reputable manufacturer.

Working for the Bill

When Rexford Tugwell, then Assistant Secretary of Agriculture, initiated the movement for a revision of the act of 1906, and leaders of Congress took up his challenge, it did not take the League long to decide to go "all out" in helping to get the law passed. The trials and tribulation, the ups and downs, the discouragements and defeats, of that five-

years-and-one-day battle have, I am sure, all been reviewed here today. But perhaps a little of the way in which the League of Women Voters worked to create understanding and support back at the grass roots will interest you. The interest aroused among thousands of women in cities, towns and villages, not only made possible enactment of the Food, Drug, and Cosmetic Law of 1938, but has also helped to make possible the good administration we have had of the law since it went on the statute books.

You have also probably been reminded today that the fight presented particular difficulties because the usual channels for building public opinion were closed. (Only three newspapers in the country gave the bill their consistent support, *The St. Louis Post Dispatch,* the *Christian Science Monitor,* and Wm. Allen White's *Emporia Gazette.*) It probably had arrayed against it as formidable a lobby as ever took up cudgels against a piece of legislation. This campaign challenged every reserve of knowledge, every resource, and every technique the League could command. But our methods of reaching small groups of women who were the informed leaders in their communities, so communities, big and little, throughout the nation, aroused public thinking on this important subject, were effective. The presence of the League representative on your program tonight is your recognition of the jobs those women did. We have an objective account of what was done which was made by Bess Furman, now a *New York Times'* reporter, who served the National League in a part time publicity capacity during that period. She later wrote that she had learned from the League that a "Recipe for Reform" was "a fine frenzy, five years and forever." She was in a sense right. After the League had studied and analyzed the bill, and made recommendations for its improvement, it was necessary that the public be made to realize that the food and drug situation was positively dangerous to every citizen in the country. That first step was what Miss Furman called—"a fine frenzy." Everywhere the League was organized, its members met in small discussion groups, to talk over the facts of the situation. They talked to their neighbors, they went out on investigation trips, they gathered cosmetic containers with deceptive false bottoms, they found out about lotions and bleaches that caused skin diseases, they bought and inspected canned foods, they found out the facts about the cousin's wife's aunt who died from headache or reducing powders. Because the press and the radio could not be used, it was necessary

for the League to build up interest by personal approach. The "fine frenzy" had to be sustained for five years. In the course of those years the League of Women Voters was joined by other organizations, who through the Women's Joint Congressional Committee helped with the work at the Capitol. The record of discussion groups, public meetings, League projects, tours of inspection, letters and telegrams to Congressmen, pre-election questioning, etc., is a long one which can not be related here. Suffice it to say that the details of what was done are interesting and impressive. The League took the position throughout that it would not be practical or wise to hold out for perfection, but that it was better to try to put through the best bill possible and then keep working for improvements. You have probably been reminded today that the five years was one of compromise after compromise, and that many times the fate of the bill hung on some mere technicality.

The Bill

It was a matter of regret to the League, that the bill which finally passed did not contain provisions for *quality labeling* of food, did not include *hair dyes* in the cosmetic subject to regulation, did not require the *listing of ingredients of cosmetics*, but on the whole we felt, as I am sure the rest of you did, that the law of 1938 was a great step forward and rejoiced in its passage.

I am sure you who have attended the sessions today have heard many interesting details of the administration of the law. I feel that we should all join in a tribute to Dr. Dunbar for the way he had made the law work in the interest of the consuming public. I hope he has told you how purple-eared mice and blinky-eyed rabbits help him to do his job. I hope he has reviewed for you some of the cases of violations which have been uncovered.

As I read these records of the 1945 judgments entered against violating manufacturers, my first thought was one of shock to think from how much we are continuously in need of protection—pop corn or cereal containing rodent hairs and excretions, candy with cat hairs and larvae in it, adulterated and misbranded "vitamin" pills. My second thought was one of deep gratitude that we have a law and an administration of that law that protects me as a consumer from inferior products. Today when I buy a pound of butter (if I can get it), I know that under the act it must contain not less than 80 per cent milk fat. The label tells me

the exact weight and by whom produced. When I buy a can of tomatoes, fruit, or any of the foods known as "standardized" products, I know that the contents of the can are required by law to meet the standards set up by the office of the Food and Drug Administration. If the product is something not "standardized," such as, we will say, "Chicken a la King," the label on that can must give me the exact ingredients of the mixture contained in the can.

Personally, I wish more people could read these pamphlets, and Dr. Dunbar's annual report. If they read about the incidents I have mentioned, about moldy butter seized, about drugs, shaving lotions, dentifrices, and hair lacquer forced off shelves because they were misbranded, I think they would become more aware of the law, more watchful of the labels when they buy, and more appreciative of the law which protects them. I was amazed that after seven years of the improved law that some manufacturers are still trying to market therapeutic devices ranging in absurdity from an electric belt supposed to cure asthma and Bright's Disease, to an irrigating device for the self-treatment of sinus infection. One manufacturer was so bold as to try to market a patent medicine to cure diabetes. Naturally, I was glad to see that he was given a large fine, accompanied by two years in jail, with a six-year suspended sentence which would be served if he ever dared to enter the drug business again.

Challenge of Vigilance

All of this leads me to say (what as a representative of the League of Women Voters, I must say), and what you as members of the bar, already know, that is—that the worn phrase, ETERNAL VIGILANCE IS THE PRICE OF LIBERTY, still is the truth in its very essence. To be effective a law needs not only sound administration but active citizen cooperation. Time and time again in this country we have seen a reform in city or county government, an improved merit system, or a change for the better in school administration, gradually die down, and conditions revert to a state bad or worse than it was before, simply because the citizens took for granted that once the reform was achieved their interest was no longer needed.

This occasion on which we pay tribute to the founders of food and drug legislation and review the progress it has made possible, should

also, I believe, be an occasion on which we face the challenge to keep the public aware of the law and what it means to all of us.

If public interest, built up with so much effort, during the five-year campaign to modernize the law, is allowed to die, the job of administration will become more and more difficult. Weakening amendments might possibly creep through the Congress, and before the consuming public could be reawakened to what is going on we could possibly lose much of the ground we have so arduously gained.

So I believe that each of us, if we are sincere in our tribute to a good law and an efficient administration of that law, should concern ourselves with creating public understanding of it. We can make it a point always to read labels. We can discuss with our neighbor why that is necessary if the law is to achieve its purpose. We can keep on the alert for signs of violation, and open our minds to the improvements the law needs to make our food and drug legislation as nearly perfect as possible.

[*The End*]

CONSUMER PROTECTION

". . . The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument and not merely as a collection of English words." *United States v. Dotterweich* (1943), 320 U. S. 277.

The National Food, Drug and Cosmetic Law Thus Instituted

---Its Relationship to NUTRITIONAL and MEDICAL SCIENCE

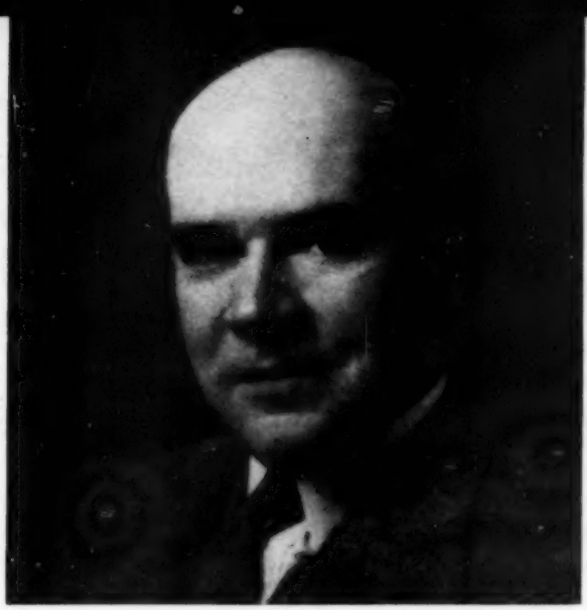
IT WAS THE DEVELOPMENT of scientific methods which gave rise to our food and drug laws for it was not until the microscope was invented and analytical methods in chemistry developed that it became possible to enact pure food and drug laws, with any hope that such laws would protect consumers against adulterated and misbranded foods and drugs.

Scientific Methods in the Development of the Food and Drug Industries

However, the relationship of science to food and drug law is more complex than the mere use of scientific methods in the preparation and enforcement of such law. For the food and drug industries, as we know them today, are themselves creatures of scientific development. Consider the 65,000 establishments in this country that manufacture food products and the 6,500 that produce drugs and therapeutic devices of various kinds. These industries, which form such an important part of our economy, owe their existence and development to advances in our knowledge made possible by scientific methods of thought.

Scientific Methods in the Enforcement of the Laws

The use of scientific methods in the development of these industries has called for scientific methods in the enforcement of the laws which regulate them. Of the 950 employees of the Federal Food and Drug Administration on January 1, 1946, some 577 were qualified in various



Frank G. Boudreau, M.D.

Executive Director, Milbank Memorial Fund; Chairman, Food and Nutrition Board, National Research Council

branches of scientific work. The Administration possesses some twenty laboratories where chemical analyses and other scientific work may be carried out. The scientific work of the Administration is not confined to routine analyses but includes investigations; that is, research, which has already affected the future of the industries. Scientific investigation may make law enforcement easier by revealing how food and drug contamination can be prevented. It is a tool which may be turned to a thousand uses.

Scope of the Talk

In the few moments at my disposal tonight I propose to relate the changing order and the shrinking world to the impact of science on society, to inquire whether our food and drug law has been sufficiently flexible to meet the new conditions continually arising in our society, and to suggest that food and drug law is bound to expand until little by little it becomes a part of international law.

The March of Science

Every scientific advance which gives rise to new ideas changes the structure of our society, either by evolution or by revolution. The invention of the printing press spread abroad the new ideas which had been quietly germinating about the dignity and the rights of man. As the structure of society was not sufficiently flexible to absorb these new ideas, the pressure grew until it burst into the French Revolution. The

invention of the machine brought the industrial revolution with its enormous increases in population, the rise of great cities and many other social and economic consequences which are still plainly evident in the modern world. No power can stop the march of science, and once science has increased our powers over nature there is no going back—the moving finger writes and having writ moves on.

For centuries knowledge advanced rather slowly but from the middle of the eighteenth century onward new inventions and new ideas came faster and faster, reaching a climax in the last forty years when science progressed as much as in the preceding two thousand years. To realize how new inventions and developments have multiplied in the last few years we have only to think of the automotive industry, the airplane, motion pictures, plastics, television, radar, rocket bombs and planes, atomic energy and new life-saving drugs like penicillin and the sulphonamides. Changes brought about by these advances are potentially just as dangerous as those brought about by the invention of the printing press or of the machine. Once you have released those forces you cannot bottle them up again. The only recourse is to harness them to constructive use for the benefit of mankind.

During the last few years nutritional science has advanced possibly faster than any other. If the knowledge of food and nutrition which we now possess could be applied for the benefit of the whole world, without regard to political frontiers, we would be at the beginning of a new era of health, happiness, and prosperity. Fortunately, we have not tried to bottle up this knowledge but have applied it to food production and to the improvement of the nutrition of the people in certain countries. Just before the war, largely because of the contribution of a few countries where farming was on a scientific basis, more food was produced than ever before in the history of the world. Food was one of the important factors in our victory over the enemy. And in the United Kingdom, Canada, and the United States, the science of nutrition was put to work to maintain the health of the people at a time when that population, particularly in the United Kingdom, was strained almost to the breaking point. In all previous wars the rates of certain important causes of death have increased. In this war, for the first time in history, new low records were reached in the United Kingdom in death rates from infant mortality, maternal mortality, prematurity, tuberculosis, and other causes which

affect the most vulnerable groups in the community. During the war we were eager to accept new ideas, but with the return of peace it is again a question whether our society is sufficiently flexible to absorb the new knowledge which science is constantly bringing forward for our use.

Federal Food, Drug, and Cosmetic Act Is Flexible

Let us examine, from this point of view, the food and drug law of the United States.

In an article on food and drug regulation in the *Encyclopaedia of Social Sciences*, published before the present Federal Food, Drug, and Cosmetic Act was adopted in 1938, Carl L. Alsberg states:

> "The enactment of food and drug standards by law has often been advocated both in this country and abroad. While such standards would make enforcement simpler, less expensive and more efficient, the existence of rigid standards difficult to change would be likely to hamper progress in the food industries and to render difficult the introduction even of meritorious new articles or new methods of manufacture. This might be avoided by delegating the authority to promulgate and to alter definitions and standards to some responsible government administrative agency."

The present Federal act avoids the unnecessary rigidity which might stand in the way of progress by precisely the mechanism suggested by Dr. Alsberg. Far from being an obstacle to scientific advance, it is so framed as to permit the Administration to consult and to take account of scientific opinion before promulgating its definitions and standards of identity.

The enrichment of flour and bread is a good example of how the act fulfils its fundamental purpose, which is to promote the health and welfare of the American people.

The Enrichment Program

To understand the significance of the enrichment program, one must remember that the lower the income the greater the amount of flour and bread commonly found in the diet, for these high calorie foods are relatively cheap. In the South where nutritional deficiencies have been common, the low income groups consume large amounts of flour and bread as well as of corn products. Surveys have shown that the diets of these low income consumers—North, South, East and West—are low in the important vitamins found in the wheat berry: thiamine, riboflavin, and niacin. Enrichment means that relatively larger amounts

of these vitamins than are found in the wheat berry are added to enriched flour and bread. Hence the low income consumer, whose diet has been low in these nutrients, and who eats large amounts of flour and bread, receives the most nutritional profit from the enrichment program.[1]

The enrichment program was initiated in 1940 by physicians and nutrition scientists who feared that a population suffering from the dietary deficiencies revealed by many surveys, would not be able to withstand the strain of war, then clearly foreseen. The cooperation of the millers and bakers was enlisted and the Food and Drug Administration was asked to hold hearings in order to promulgate definitions and standards for enriched flour and bread. Hearings were held and definitions and standards adopted. Thus the Federal Food, Drug, and Cosmetic Act has been helpful in bringing about a great national nutritional improvement. For by adopting definitions and standards for enriched bread and flour it made possible a great cooperative enterprise on the part of nutrition scientists, millers, and bakers. Millers and bakers were under no compulsion to produce enriched flour and bread; all the law required was that flour and bread labeled "enriched" must conform to the standards adopted. Nevertheless, a year or two after the campaign got under way from 75 to 80 per cent of the white flour and bread sold in this country was enriched purely on a voluntary basis. Early in 1943, the War Food Administration adopted an order requiring the enrichment of all white bread and rolls, and more recently the Secretary of Agriculture has ordered an increase in the extraction rate of wheat, from around seventy per cent to eighty per cent. The millers and bakers have agreed to continue the enrichment of this slightly darker flour and bread so that the nutritional reform, begun in 1940, still continues. About half of the states have now enacted laws requiring enrichment of white flour and bread up to Federal standards so that in these states this nutritional reform will be permanent. The Food and Nutrition Board of the National Research Council, representing the nutrition scientists of the country, has for some time been preparing to deal with the improvement of corn products which are so popular in the South where their use is associated with the prevalence of pellagra. Hearings under the Food, Drug and Cosmetic Act, have already been held, and presently action

[1] Two important minerals, iron and calcium, are also required and optional ingredients respectively of enriched bread and flour.

of the Food and Drug Administration will, no doubt, open the way for another advance towards the better nutrition of our people.

We may, therefore, conclude that the Food and Drug Law is not so inflexible and rigid as to stand in the way of scientific advance. On the contrary, it is flexible and adaptable enough to permit the use of current advances in our knowledge of nutrition for the health and welfare of our people.

Medical Science Has Not Lagged Behind

If, in recent years, the science of nutrition has forged ahead, medical science has not lagged behind. The development and use of penicillin alone illustrates everything I have said concerning the impact of scientific advance on society. For the growth of populations is due to the excess of births over deaths, and when changes occur in one of these factors, the balance of population is affected. In countries with the highest birth rates the expectation of life is low partly because of the inroads of infectious diseases. In the United States expectation of life at birth is 64 years; in many Far Eastern countries it is 40 years or under. In a short time science will bring to the help of these people the healing of penicillin and the suphonamides and the insect-destroying qualities of DDT and other new pesticides. Death rates from malaria and other infectious diseases will be reduced, expectation of life will be increased, the excess of births over deaths will become greater, and the rate of growth of the population will become far more rapid than it is today. I leave to your imagination the political, social, and economic consequences which might flow from a rapid increase in the population and a shifting of the age distribution in those underprivileged countries already populated with teeming millions who aspire to the same freedoms and standard of living as their brothers enjoy in the West.

Tennyson has spoken of the fairy tales of science, and the achievements of science in the field of food and drugs resemble fairy tales in their unbelieveable scope and splendor. But their impact on our society is no fairy tale, and it is clear that man will have to use the cunning of serpents and the wisdom of the dove if he is to adapt his social institutions to the changes brought about by scientific advances in these fields.

Penicillin, the sulpha drugs, atabrin, blood plasma, insulin and many others are powerful medicaments; what the French call heroic

remedies. Their potency must be assayed, they must conform to a standard, their purity must be assured, and their dosage must be exact. The pharmacist who dispenses these drugs and the physician who prescribes them must know their business; for to place them in untrained hands would be like giving children dynamite to play with. So the laws which safeguard their quality, integrity, and potency must be well thought out and intelligently enforced; they must be flexible enough to permit of scientific advance and strong enough to prevent danger to human life.

International Cooperation

I should like to emphasize that we in this county could not have succeeded in preventing the abuse of certain drugs had we not joined with other countries in drafting, adhering to, and enforcing an international convention which is simply another name for international law. No doubt you are all familiar with the international opium conventions which govern the production, import, and export of opium and its derivatives. The machinery set up by the conventions is complicated but it may be described as a kind of governing council which scrutinizes the estimates of opium needs submitted by each country, judges whether those estimates are reasonable and then issues certificates permitting that country to import its quota. The working of the convention has been likened to the beginnings of world government; it has succeeded so well that the world may well be encouraged to attempt it in other fields.

On the positive side we have international biological standardization, which has not yet been written into international law but depends for its enforcement on understanding among scientists and incorporation into the pharmacopœia of the various countries.

Biological standardization did not take form or substance until it was made the subject of League of Nations action in the early 1920's. Penicillin was the last medical preparation standardized by the League, and soon throughout the world a unit of penicillin will mean exactly the same thing in every country.

To illustrate the meaning of biological standardization, one may imagine a diabetic starting out for a voyage around the world. He carries with him a letter from his physician stating that for the treatment of his condition he requires so many units of insulin at such and such

intervals. But what is a unit of insulin? Before it was standardized by the League of Nations, it varied in potency from country to country. The number of units prescribed by his physician might mean too big a dose in one country and too little in another. Soon the unfortunate traveler would sicken or die or be forced to give up his journey.

Such standardization needs to be controlled, else the medical preparations in the different countries will soon vary in potency. Every important country has a national center which tests the products manufactured in that country by comparing them to national standards. In turn the national standards are compared with the international standard at a laboratory acting on behalf of the League of Nations.

Preparations Standardized Under League of Nations Auspices

More than thirty important preparations used in medicine have been standardized under the auspices of the League of Nations. These include diphtheria and other antitoxins, antipneumococcus and other sera, tuberculin, test sera for blood groups, digitalis, thyroid extract and other powerful drugs, vitamins, sex hormones and penicillin. The day may not be far off when this standardization will be written into a convention which will become the first of a series of world drug laws. Nor is it unlikely that there will be a world food law as well. National food and drug laws prohibit the import of foods which are impure, a danger to health, or adulterated. Obviously the best way to handle this problem is by international agreement. And if we advance to the point of having an international food and drug law, why not an international pharmacopœia, which would become a common language for physicians, pharmacologists and pharmacists throughout the world, enabling them to understand and profit by the experience of their colleagues in other countries? This is, in fact, an old dream which certain internationally-minded scientists have sought to realize for many years. Begun in Belgium, the work was turned over to the League of Nations, where some progress has been made even during the difficult years of the war. Biological standardization and the preparation of a world pharmacopœia will, no doubt, be taken over and carried on by the new world health organization of the United Nations.

Our Food and Drug Laws May Be Adapted to a Changing World

So our food and drug laws which we celebrate tonight are well adapted to the changes in our social structure caused by the advance of

science. They help scientists, food and drug manufacturers and government to use these advances for the health and welfare of the people. By wise amendment and suitable regulation these laws may be adapted to a world which is ever changing under the impact of scientific advance.

And just as our food and drug laws began in the towns and progressed to the states and then to the Federal government, the laws of the latter in turn affecting and unifying the laws of the states, so we can foresee the extension of these laws to the entire world, and international law in turn affecting the laws of the less advanced countries.

More than a hundred years ago, in Victorian England, a poet dreamed dreams and saw visions, he saw that a time would come when

> ". . . the war-drums throbb'd no longer, and the battle-flags were furl'd
> In the Parliament of Man, the Federation of the world."

And he prophesized that

> "There the common sense of most shall hold a fretful realm in awe,
> And the kindly earth shall slumber, lapt in universal law."

[*The End*]

INTERNATIONAL DISTRIBUTION OF THE U. S. P.

Since 1908, the various editions of U. S. P. have been translated into the Spanish language. Such was the case with U. S. P. XII, and consideration is again being given to having the same done with U. S. P. XIII. The Spanish edition of the U. S. P. is now recognized as the official pharmacopœia in the following countries: Costa Rica, Cuba, Dominican Republic, Nicaragua, Panama, Philippine Islands, Puerto Rico and Uruguay. A number of other South and Central American countries are considering similar adoption. From releases concerning the U. S. P., dated May 29 and June 5, 1946.

The National Food, Drug and Cosmetic Law Thus Instituted

A JUDGE'S TRIBUTE

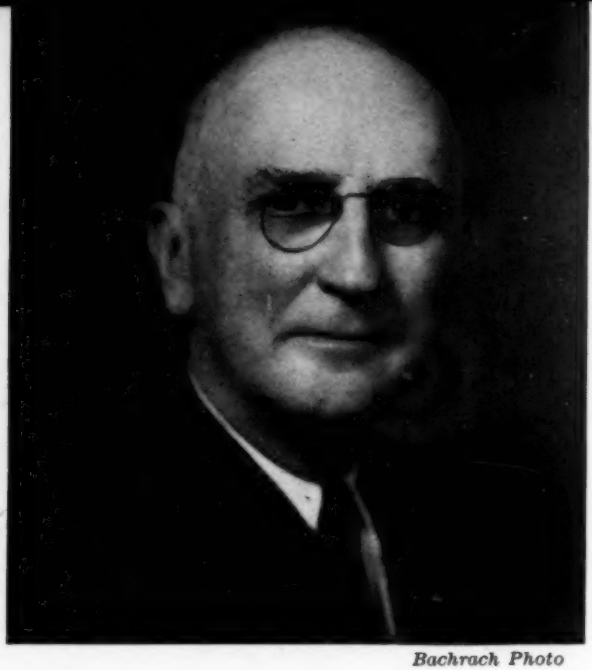
John C. Knox . . . Senior Judge, United States District Court for the Southern District of New York

Judge Knox was prevented by illness from delivering his address at the New York meeting

IN RISING TO ADDRESS you this evening, I should like, first of all, to express my appreciation of this opportunity to participate in the celebration of the fortieth anniversary of the enactment of the original Federal Food and Drug Act. For 33 of those years, I have had a good deal to do with the enforcement of that statute. From 1913 to 1918 I was an Assistant United States Attorney for this judicial district. Over the succeeding 28 years, I have been a Federal judge. In each of these capacities, I have had occasion to observe the beneficence of the law for which Dr. Wiley was largely responsible.

Tribute to Dr. Wiley

Had it not been for his appreciation of the necessity that the populace should have pure food, and that our people should be protected against the wiles and impositions of charlatans and extortioners, God alone knows what would be the present state of the public health. For Dr. Wiley's courage and foresight, for his determination and tenacity of purpose, and for the great boon he has conferred upon suffering humanity, I pay him tribute, and render my thanks. May I say, also, that it is a source of gratification that I have been permitted to execute the terms and purposes of the statute, and to adhere as closely as was possible to the ideals that Dr. Wiley espoused.



Bachrach Photo

John C. Knox

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"I have had occasion to observe the beneficence of the law for which Dr. Wiley was largely responsible."

The Public Is Gullible

In my effort so to do, I have become convinced of several things. One of these is that the public, notwithstanding its education, intelligence and self-interest, is extremely gullible. Another is that this world of ours is filled with a greater number of fraudulently disposed persons than one naturally would imagine. A further conclusion to which I have come is that we hail the law as our shield and buckler, provided that it be not directed against either ourselves or the class to which we belong. Let me illustrate.

Illustrative Cases

In days gone by, the public was an avid purchaser of a certain type of mineral water. In their belief, it was a veritable elixir of life, and was shipped directly from the spring of Ponce De Leon in Florida. The water, as a matter of fact, was probably efficient as an irrigant, and so far as I know, was not deleterious to health. But listen to the text of its label. It is reminiscent of what went on in days gone by. I quote:

"The World's Greatest Remedy For the Following Ailments In Their Most Chronic Forms: Rheumatism, Constipation, Kidney Diseases, Liver Complaints, Dyspepsia, Biliousness, Sick and Nervous Headache, Scrofula, Malarial Fever, Hay Fever, Typhoid Fever, Lumbago, Sleeplessness, Vertigo, Piles, Skin Disorders,

Indigestion, Jaundice, Flatulency, Female Complaint, Neuralgia, Colds, LaGrippe, Palpitation of the Heart, Disordered Nerves, Dysentery, Gout, Bilious Colic, Stomach and Bowel Troubles, Loss of Appetite, Catarrh in All Forms, Gall Stones, Dropsy, Bladder Troubles, And All Diseases Arising From a Disordered Liver, Kidneys, Stomach and Impure Blood. A Mild Aperient Tonic And a Perfect System Regulator. Sold Only by Authorized Agents."

In these modern times, we hear much concerning the curative qualities of penicillin and sulpha drugs in affording relief from the ills to which human flesh is heir but, great as may be the benefits to be derived from latter day discoveries, they fall far short of the claimed virtues of the water that came from Crab Orchard Springs.

The wanton, reckless and fraudulent statements contained in the label from which I have read are now recognized as being preposterous and ridiculous. The fact is, nevertheless, that as recently as May 17, 1921, the public was buying Crab Orchard water, and that label was seriously and vigorously defended as a truthful and legitimate description of the therapeutic value of the article it advertised. It may be that we have not come as far as we had hoped.

Cherry Case

In this connection, let me tell you of a case that came before me a few years ago. I was holding court in the Western District of New York, and that area, as you may know, includes the magnificent fruit belt that is superinduced by its proximity to lakes Erie and Ontario.

When I went on the bench one morning, I was confronted with a case entitled *The United States against One Carload of Cherries.* On looking over the papers, I saw that the claimant of the cherries, a well-known cannery located in Chautauqua County, was resisting the government's seizure of its fruit, and that it had demanded—as was its right—that the issues be tried before a jury. That body was made up, of course, of citizens of Western New York, and some of them were farmers and fruit growers.

The charge was that the canned cherries in this car were rotten, putrid, wormy and unfit for human consumption. This charge, however, was vigorously denied, and a prominent lawyer, and a former judge, in Western New York, had been retained to defend the character of the cherries.

When all preliminaries were out of the way, and witnesses began to testify, we were told that a gallon can contains about 860 cherries and,

in so great a number, the Pure Food and Drugs Act is generously willing, under what is called "a range of tolerance" to allow the presence of a few worms—say eight or ten. But, in this instance, some eighty or ninety worms floated serenely within the liquor of each can. In addition, a goodly number of "rots" and "spots" characterized the contents of each container.

The plant that had canned the pack was cooperatively owned, and its shares were in the hands of nearby farmers and fruit growers. To them the loss of a carload of cherries meant the loss of a year's profit, and, from their standpoint, it was important that the cherries be not condemned. We had not proceeded far when the case developed into a scientific contest between entomologists. As the facts were unfolded, the jury and I were led behind the scenes and made acquainted with the most intimate secrets in the life of the "cherry fly."

This creature, we were assured by an eminent scientist from Cornell University, is a "clean feeder." He—or it—or so it was said, never came in contact with filth. Furthermore, it shuns offal and manure piles as it would the plague—but it fairly loves cherries. Feeding, as it does, only on clean fruit, we were told that a cherry worm would be no more harmful to human diet than an oyster or a shrimp. It was argued that the "worms" to which the government had taken exception, were, in reality, nothing more than cherry-fly larvae, which had developed within a cherry that had been stung by an adult fly. They were not, therefore, either to be treated scornfully or regarded as deleterious to health. I have no doubt of the basic truth of the witnesses' testimony. At the same time, I had a feeling that so far as I personally was concerned, I would prefer to have my oyster stews served in a bowl instead of out of a piece of pie crust. I thought, too, that this might also be the preference of the professor. With this in mind, I turned to him and said: "Doctor, I've been greatly interested in your testimony—so interested, in fact, that I feel impelled to ask you a very searching question." He replied "I'll be glad to answer if I can, your Honor." "You are a married man?" I asked. "Yes." "Then suppose," I began, "that when you left home this morning, your wife had asked you to bring her a can of cherries to enable her to bake a cherry pie. Suppose, again, that when you entered the grocery, you saw two brands of cherries on the shelves. One of them is from the lot before us. The other brand is one that you know to

be free of worms. The quality otherwise is the same, and the price is also the same. Which one would you take home?" The professor thought a moment, and then, slowly replied "Well, to tell you the truth, your Honor, I would take the can that contained no worms." "In view of your testimony," I asked, "Why would you do so?" The answer was "Merely because of preconceived ideas."

Shortly thereafter, the case went to the jury, and I assumed that they would shortly return with a verdict in favor of the government. For hours and hours I waited, and finally, having an appointment for dinner, I ordered a sealed verdict and left the court house.

On taking the bench the following morning, I was informed that the jury had reached an agreement at about 10 o'clock the previous evening. The jury was now in the box once more, and I opened the sealed verdict. To my great surprise, it read

"We, the jury, empanelled in the case of *The United States against One Carload of Cherries*, find a verdict in favor of the cherries."

I suppose I looked aghast. It may even be that the jury feared that I might verbally assault them. In any event, the foreman of the jury, a farmer, rose to his feet and searched nervously within an inside pocket. Finally, with a sigh of relief he pulled out a sheet of paper and said "Your Honor, the jury found two verdicts in this case, and I'd like you to know what this one says." "Go ahead and read it," I replied. "I'd like to hear it." "We, the members of the jury" he read, "recommend to the stockholders of the canning company that they call a meeting at once and put new officers and managers in control of the plant. It will be very harmful to the fruit industry of Western New York if cherries such as these are shipped over the country. No such pack should ever have been put out, but, inasmuch as the stock of the cannery is owned by the local fruitgrowers, and since they did not know of the condition of the pack, and since its seizure would inflict losses upon them that they can't afford, we decided to give our verdict in favor of the cherries."

This naive apology gave me, of course, a perfect basis on which to set the verdict aside, and that I did. This action was followed by negotiation between the government and the cannery, with the result that the cherries were reconditioned. Thereby, the loss was less than would have been the case had the shipment been condemned and destroyed.

Enforcement of the Act Sometimes Attended by Considerations of Human Nature

This episode is brought to your attention, not alone by reason of its amusing character, but to enable you to understand, as I have previously indicated, that the enforcement of the pure food and drug law is sometimes attended by considerations of a human and practical nature. In other words, there are occasions when a particular set of facts will make an *ad hominem* appeal to jurors who are themselves honest, upright and intelligent. This is true, also, when medications that are not viciously harmful, but are, at least, inert and ineffective, come before a jury. The truth is, of course, that as a nation, we are not far removed, in some respects, from a state of primitive civilization. Our forefathers had to doctor themselves. It followed that one generation after another has handed down to us a variety of concoctions of roots, herbs, barks and berries that are reputed to have proved and established virtues. As a matter of fact, for some of them, I will myself gladly testify. Hence it is, when Aunt Minnie's Drawing Salve, Farmer Ben's Live Killer and Dr. Wheaton's Vermifuge gets before a jury, the government does not always win its case. Indeed, in such instances, the government is frequently defeated.

Another Illustrative Example

Indeed, years ago, in the country where I was born and raised, a certain patented medicine was widely advertised, and widely used. I might add, that this was a local option community and the sale of whiskey, as such, was contrary to law. The medicine to which I refer was said to be a sure-cure for any and every disease that mankind knows. Its name, as I recall, was the euphonious and descriptive word "Correcta." For one ailment at least, "Correcta" was a temporary specific. To this, I'll take a solemn oath. I've seen it work. And, against "Correcta" the government would have no chance. The story is this:

Six lads, together with myself, lived in a boarding house, and our landlady was one of the most estimable women who ever lived. Without assistance, she cleaned our rooms, made the beds and cooked our meals. But, as the Spring term of college came along, she began to tire, and suffer fatigue. After a while, those symptoms began to be pronounced. It thus came about that she entered the diningroom one morning and

sat at the table. Folding her arms under her apron, she lifted her weary eyes, looked in our faces, and said:

"Boys, you'll have to find another boarding house. I just can't stand this work a day longer."

We were aghast! Examinations were just ahead of us. Every boarding house in town was full and overflowing. None of us could afford to take his meals at the hotel, and our situation was desperately serious. Each of us offered to make his own bed and to clean his room, and to do it well. But this was to no avail. She mournfully shook her head and said:

"No boys, I can't do it, I just can't carry on. You'll have to find a new boarding house by Saturday night. I just want to go to bed and to rest, rest and rest."

There we were facing a condition, and not a theory. That condition called for immediate action, and one of us rose to the occasion. He suggested that he be permitted to supply the landlady with a bottle of "Correcta." She said that while she had seen the article advertised, and had heard that it was very good, she had never taken any of it herself. The lad remarked that if she permit him, he would supply her with a bottle that very morning, and out he went. Within a quarter of an hour, he had returned, and in his hand was a bottle of "Correcta." Very carefully, he gave directions as to its use, and all of us hurried away to our respective classrooms. When evening came, and we returned to the boardinghouse, we got the aroma of sizzling steak, together with the odor of browned biscuits. As we stood sniffling at the scents from the kitchen, we heard the humming of a tune, and the voice was that of the woman who had been so tired. "Correcta" had done its work, and done it well. Over the remaining three weeks of the school year, we supplied our landlady with nine bottles of "Correcta". Meanwhile, we lived on the fat of the land. When school was over and done, we packed our trunks and went to say "Goodbye" to our hostess. She kissed each of us. When she came to the lad who had suggested "Correcta," she kissed him twice, and said

"Thank you so much for 'Correcta.' It's the best medicine I've ever had."

We wanted her to continue to feel that way. She was a prohibitionist. For that reason, we didn't tell her that the base of "Correcta" was 40 per cent alcohol.

"Correcta," my friends, now belongs to the ages. I doubt, however, if the whiskey we get today was any better than that which brought peace, solace and joy to a woman whose memory I revere and cherish.

Conclusion

But, be that as it may, one thing is certain. The deceitful advertiser, the blood-sucking leeches of the medical profession, the rapacious exploiters and purveyors of slime and filth can no longer, with impunity, practice and engage in their despicable and nefarious deeds. Into their hearts and minds, the work of Dr. Wiley has effectively put the fear of criminal punishment. The result is that today we can eat, drink, paint our lips, dose ourselves, and prescribe for our friends, with a reasonable assurance that we shall live for at least the next 48 hours. For this assurance, we can thank God, and take courage. [*The End*]

Organizations Participating in Commemoration Meeting

The official organizations represented at the meeting to commemorate the original Federal Food and Drugs Act included: Association of Food and Drug Officials of the United States, and Association of Official Agricultural Chemists. The professional organizations (in addition to the New York State Bar Association) included: American Medical Association, New York Academy of Medicine, Society of Medical Jurisprudence, American Pharmaceutical Association, and American Nurses Association. The consumer organizations included: General Federation of Women's Clubs, National League of Women Voters, American Home Economics Association, American Dietetic Association, American Association of University Women, National Council of Jewish Women, National Board of Young Women's Christian Association, and National Women's Trade Union League of America. The food industry organizations included: Grocery Manufacturers of America, Inc., National Canners Association, National-American Wholesale Grocers' Association, United States Wholesale Grocers' Association, National Association of Food Chains, *et al.* The drug industry organizations included: American Pharmaceutical Manufacturers' Association, American Drug Manufacturers Association, Proprietary Association of America, National Wholesale Druggists' Association, and Federal Wholesale Druggists' Association. The cosmetic industry was represented by the Toilet Goods Association.

An Announcement

NOW IN PREPARATION for early delivery is a special volume bringing together in permanent and appropriate book form the memorabilia of the Historic Meeting to Commemorate the Fortieth Anniversary of the Original Federal Food and Drugs Act.

Included will be not only the full text of all the papers, but also portraits and photographs, and tributes, messages, and greetings from public and private personages, and leaders in participating industries and in civic affairs.

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